EPA Reg. Jacket 39967-71 Vol. 1

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branches

ORIGINATOR/PRODUCT REVIEWER: Tom Lominello				**RMB II**	**TEAM** 34
Decision No: 485280		**Submission No:** 943558		**EPA File Symbol/Reg No.**	
PRIA Fee: $_____		**Action Code:** [illegible] 362		39967-71	
GPRA:	**FQPA**	**Non-FQPA**		**Product Re-reg.**	
PRIA:	**ME-TOO**	**New Use** ☐	**Old Chemical**	**New Chemical** ☐	**Amend w/data**

	MONTH	DAY	YEAR
APPLICATION DATE	11	11	2013
EPA PIN DATE	11	13	2013
DATE PM RECEIVED FROM FRONT END			2013
DATE SENT TO SCIENCE			2013
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			**DATE DUE OUT OF AGENCY** 2/11/2014

Type of Data:	**PSB Product Chemistry**	**PSB Acute Toxicology**	**PSB Efficacy**	**RASSB Environmental Fate**	**RASSB Ecological Effects**	**RASSB Chronic Toxicology**	**RASSB Exposure/ Residue**
	X						

Comments: Please provide hard and electronic copy of deliverable(s).

Minor Formulation Change

Product Chemistry: Pls review CSFs 4-7

Registrant is adding new source of ai

Tom's package has been given to Karen
There are xtra copies

Decision #: 485280
DP #: (416318)
NON PRIA
Parent DP #:
Submission #: 943558
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 06-Feb-2014

* * * Registration Information * * *

Registration: 39967-71 - PREVENTOL A 14-D

Company: 39967 - LANXESS CORPORATION

Risk Manager:

Risk Manager Reviewer: Thomas Luminello, Jr. TLUMINEL

Sent Date: PRIA Due Date: 11-Feb-2014 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients: See page 2

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 25-Nov-2013 Due Back:

DP Ingredient: See page 2

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ○ Yes ● No Parent DP #:

Assigned To	Date In	Date Out		
Organization: AD / PSB	23-Jan-2014		Last Possible Science Due Date:	28-Dec-2013
Team Name: CTT	23-Jan-2014		Science Due Date:	
Reviewer Name: Negron, Juan	05-Feb-2014	06-Feb-2014	Sub Data Package Due Date:	
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Please reveiw CSFs 4-7. Registrant is adding new sources of active

DP#: (416318) *** Product and Data Package Ingredients *** Decision#: (485280)

PC Code	CAS	Ingredient Name
035505	330-54-1	Diuron
128872	10605-21-7	Carbendazim
099901	26530-20-1	Octhilinone
099901	26530-20-1	Octhilinone(3%)
128872	10605-21-7	Carbendazim(10%)
035505	330-54-1	Diuron(22%)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 14, 2013

OFFICE OF CHEMICAL
SAFETY
AND POLLUTION
PREVENTION

LUANNE JERAM
LANXESS CORPORATION
111 RIDC PARK WEST DRIVE
PITTSBURGH, PA 15275-1112

PRODUCT NAME: PREVENTOL A 14-D
COMPANY NAME: LANXESS CORPORATION
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 39967-71
EPA RECEIPT DATE: 11/13/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at {703-308-6416}.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {943558K~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 34

Receipt No. S-	943558
EPA File Symbol/Reg. No.	39967-71
Pin-Punch Date:	11/13/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

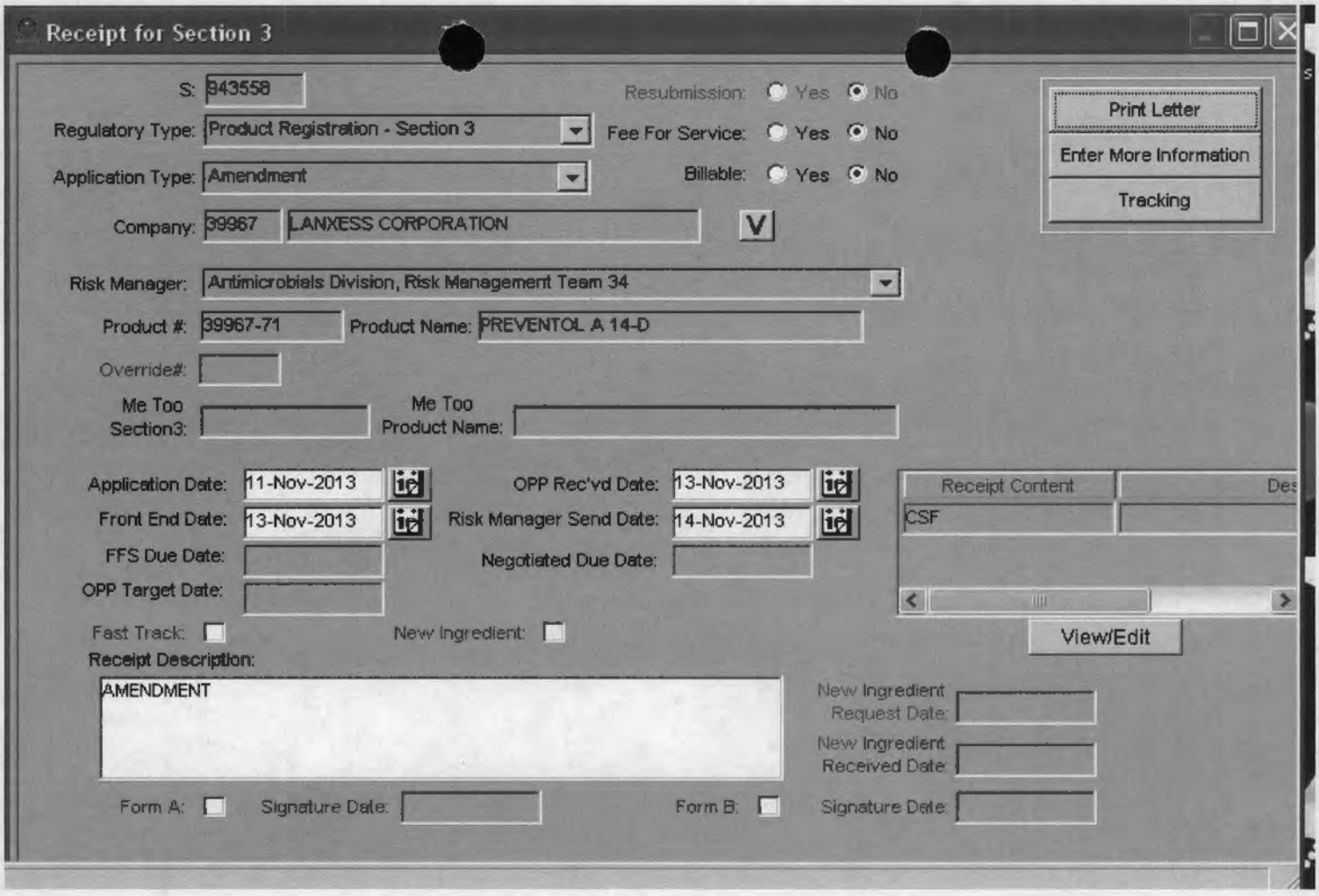
Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Team 4 Date: 11/14/13

Remarks: New alt. source of a.i.

*Does this change require confirmatory efficacy data?


Receipt for Section 3
S: 943558
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Company: 39967 LANXESS CORPORATION
Print Letter
Enter More Information
Tracking
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 39967-71
Product Name: PREVENTOL A 14-D
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 11-Nov-2013
OPP Rec'vd Date: 13-Nov-2013
Front End Date: 13-Nov-2013
Risk Manager Send Date: 14-Nov-2013
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
AMENDMENT
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

TRANSMITTAL DOCUMENT

Name and Address of Submitter:	LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112
Regulatory action in support of which this package is submitted:	**Information to add alternate CSFs to PREVENTOL A14-D (EPA Reg.No. 39967-71)**
EPA Reg. No./File Symbol:	39967-71
Alternate test material name	
Transmittal Date:	November 11, 2013

Administrative Materials

	Transmittal Document Cover Letter
EPA Form 8570-1	Application for Pesticide
EPA Form 8570-4 (4 CSFs)	Confidential Statements of Formula (Alternate 4, 5, 6, 7)
	Material Safety Data Sheets

Volume No.	Citation	MRID Number
1	Administrative Materials (3 copies)	

Product Name:	**Preventol A14-D**
Company Official:	Luanne Jeram
Company Name:	LANXESS Corporation
Company Contact:	Phone: 412-809-4773 E-mail: luanne.jeram@lanxess.com

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[X] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company / Product Number: 39967-71
2. EPA Product Manager: Jacqueline Campbell
3. Proposed Classification: [x] None [ ] Restricted
4. Company / Product (Name): PREVENTOL A14-D
PM#: 34
5. Name and Address of Applicant (*include ZIP Code*)
LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112
[ ] *Check of this is a new address*
6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No.
Product Name

Section - II

[X] Amendment - Explain Below.
[ ] Resubmission in response to Agency letter dated
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated
[ ] "Me Too" Application
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
This is being submitted as a minor formulation amendment to add four alternate confidential statements of formula (4 through 7). Additional details are provided in the cover letter.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No		[ ] Yes [ ] No		[ ] Metal [ ] Plastic
***Certification must be submitted**	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package Wgt	No. per container	[ ] Glass [ ] Paper [ ] Other (Specify)

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) retail Container
5. Location of Label Directions
6. Manner in Which Label is affixed to Product: [ ] Lithograph [ ] Paper glues [ ] Stenciled [ ] Other

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application.)

Name	Title	Telephone No. (Include Area Code)
Luanne Jeram	Head, Regulatory Affairs, MPP NA	412-809-4773

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature: Luanne Jeram
3. Title: Head, Regulatory Affairs, MPP NA
4. Typed Name: Luanne Jeram
5. Date: 11/11/13
6. Date Application Received (Stamped)

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Pages 10-21 Inert & product ingredient source information may be entitled to confidential treatment

LANXESS
Energizing Chemistry

November 10, 2013

VIA COURIER

Luanne Jeram
Material Protection Products
Regulatory Affairs
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-4773
Fax 412-809-1068
luanne.jeram@lanxess.com
www.US.LANXESS.com

Ms. Jacqueline Campbell
Document Processing Desk (AMEND)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Product: PREVENTOL A14-D
Registration #: 39967-71
Application for Minor Formulation Amendment – addition of Alternate Confidential Statements of Formula (4 through 7)

Dear Ms. Campbell:

Enclosed is a minor formulation amendment requesting the addition of four alternate confidential statements of Formula.

These reflect the use of Preventol A6 (EPA Reg. No. 39967-84) as the source of diuron. Safety Data Sheets for the inert ingredients are also provided.

Specifically enclosed are:

1. Application form (EPA Form 8570-1)
2. Four alternate confidential statements of formula (4,5,6,7)
3. Safety Data Sheets for the following inert ingredients:

[redacted]

Please feel free to contact me at 412-809-4773 with any questions.

Sincerely,

Luanne Jeram
Head, Regulatory Affairs, MPP NA

Inert ingredient information may be entitled to confidential treatment

TASK ASSIGNMENT FORM
Antimicrobial Division/Regulatory Management Branches

ORIGINATOR/PRODUCT REVIEWER: Stacy Griffith				**RMB II**	**TEAM** 34
Decision No: 480625		**Submission No:** 936248		**EPA File Symbol/Reg No.** 39967-71	
PRIA Fee: $_____		**Action Code:** 362			
GPRA:	**FQPA**	**Non-FQPA**		**Product Re-reg.**	
PRIA:	**ME-TOO**	**New Use** ☐	**Old Chemical**	**New Chemical** ☐	**Amend w/data**

	MONTH	**DAY**	**YEAR**
APPLICATION DATE	5	31	2013
EPA PIN DATE	6	3	2013
DATE PM RECEIVED FROM FRONT END			2013
DATE SENT TO SCIENCE			**2013**
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			DATE DUE OUT OF AGENCY: 9/1/2013

Type of Data:	**PSB Product Chemistry**	**PSB Acute Toxicology**	**PSB Efficacy**	**RASSB Environmental Fate**	**RASSB Ecological Effects**	**RASSB Chronic Toxicology**	**RASSB Exposure/ Residue**
	X						

Comments: Please provide hard and electronic copy of deliverable(s).

Minor Reformulation Change

Product Chemistry: Pls review alternates 4-11

Registrant changing source of ai as well as modifying inert ingredients in the formulation

Material Sent for Data Extraction

Reg # 3994771

Description: 362

☐ Material(s) Sent to Data Extraction Contractors:

- ☐ New Stamped Label Dated _____
- ☐ Notification Dated _____
- ☐ New CSF(s) Dated _____
- ☐ Other: _____

☐ Decision #: 480625

☐ Other Action/Comments: _____

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Stacey GRIGSBY

Phone: 305.4440 Division: AD

Date: 8/29/13

Created February 3, 2011

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 29 2013

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Barbara Sadler
LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Subject: **Phenocide 128**
EPA Registration No.: 39967-71
Application Date: May 31, 2013
Receipt Date: June 3, 2013

Dear Ms. Sadler:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 3(c)7a, as amended, is acceptable.

Proposed Amendment:

- Revise Alternate Confidential Statement of Formula #s1-4: Adding Registered Source

General Comment:

The basic and alternate formulation#s1-4 dated, 5/30/13 are not acceptable because you must adjust the amount in column 13b of the CSF so that the nominal concentration of the active ingredient is 10% as per the product label.

Should you have any questions or comments concerning this letter, you may contact me by telephone at (703) 308-6416 or by e-mail at campbell-mcfarlane.jacqueline@epa.gov or Stacey Grigsby by telephone at (703) 305-6440 or by e-mail at grigsby.stacey@ epa.gov during the hours of 8:00am to 4:00pm EST.

Sincerely,

Jacqueline Hardy
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

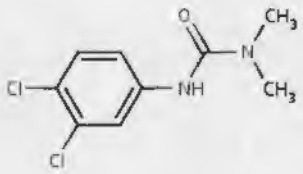
EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

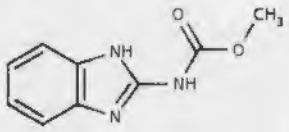
July 23, 2013

EPA Reg#: 39967-71		DP Barcode: 412935	
		Submission #: 936248	
Product name: Preventol A 14-D		Registrant: Lanxess Corporation	
Reviewer's name: Juan F. Negrón		AD/PSB/CTT- Product Chemistry	
Agency due date: 09/01/13		PSB received date: 07/03/13	
CTT received date: 07/03/13		Science due date: 07/09/13	
Formulation type: EUP.			
Integrated system: []	Non integrated system:[X]	Food use: []	Non food use: [X]
Action Code: 362	Date Completed: 07/23/13		

PC Code(s)	CAS #(s)	Active Ingredient Names	% wt (label)
035505	330-54-1	Diuron	22



128872	10605-21-7	Carbendazim	10



099901	26530-20-1	2-n-Octyl-4-isothiazoling-3-one	3

Approver: Karen P. Hicks	Approved date: 07/23/13
Comments:	

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Antimicrobials Division (AD)

July 23, 2013

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 39967-71
Product name: Preventol A 14-D
DP # 412935

From: Juan Negron, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Jacqueline Campbell-McFarland / Stacey Grigsby
PM Team 34
Antimicrobials Division (7510P)

APPLICANT: Lanxess Corporation
Action code: 362
Due date: 09/01/13

Product Formulation
Active Ingredient(s)

	% by wt.
Diuron	22
Carbendazim	10
2-n-Octyl-4-isothiazoling-3-one	3

BACKGROUND:

The registrant, Lanxess Corporation, has submitted an amendment to add eight alternate Confidential Statements of Formula (CSFs). The purpose of the amendment is to add a registered source for one of the active ingredients (AIs) and to add a registered source for [redacted] as an inert ingredient. The Product Chemistry reviewer has reviewed the following documents:

- A letter, dated 05/30/13.
- Transmittal document, dated 05/31/13.
- Application for pesticide amendment, dated 05/30/13.
- Confidential Statements of Formula (CSFs), dated 05/30/13, for alternate #s (4 thru 11) formulations.
- MSDS for co-solvent, surfactant, [redacted]

FINDINGS:

1. One of the co-solvent suppliers, [redacted] has not been included on the CSF.

2. The trade name for one of the [redacted] needs to be added on the CSF. **See confidential appendix CBI.**

3. The trade name for one of the surfactants needs to be added on the CSF. The trade name is not in the Agency database. **See confidential appendix CBI.**

4. The trade name for one of the [redacted] needs to be added on the CSF. **See confidential appendix CBI.**

5. The registrant is using a registered source for [redacted] as an inert ingredient. No study has been submitted to show that the registered product is not enhancing the efficacy of the current formulation.

6. The proposed [redacted] contains components that are not similar to the basic formulation.

7. The CSFs, dated 05/30/13, for alternate #s (4 thru 11) formulations are revised.

8. The CSFs and the label do not have the same nominal concentration for one of the active ingredients (AIs). One of the AIs shows on the label a nominal of 10% however, calculation shows 9.91%.

9. All components meet the EPA Standard Certified Limits.

Inert ingredient information may be entitled to confidential treatment

CONCLUSIONS:

The CSFs, dated 05/30/13, for alternate #s (4 thru 11) formulations are not acceptable. The proposed amendment is not acceptable.

RECOMMENDATIONS:

1. The registrant must include the supplier, [redacted] in column 11 of the CSF as an alternate supplier to be used as co-solvent.

2. The registrant must include the trade name for one of the [redacted] to be added on the CSF.

3. The registrant must contact the supplier so the supplier can provide to the Agency the full compositional data for one of the surfactants. The surfactant needs to be added on the CSF. The trade name is not in the Agency database. **See finding #3 and confidential appendix CBI**.

4. The registrant must include the trade name for one of the [redacted] on the CSF. **See confidential appendix CBI.**

5. The registrant must adjust the amount in column 13a of the CSF so that the nominal concentration of the AI is 10% as per label.

Inert ingredient information may be entitled to confidential treatment

Confidential Appendix
CBI

EPA Reg # 39967-71 DP# 412935 Preventol A14-D

[redacted]

CHEMICAL ME/PESTICIDE CHEMICA CODE (PCC) REQUEST FORM

CR# 13-073

REQUESTOR NAME: Juan F. Negrón			Request date: 07/23/13
Tel: 703-308-8116	ORG.: AD	ROOM: 8848	MAIL CODE: 7510P

CSF ATTACHED:
[x] YES If CSF is attached complete Item A and the chemical name in item C.
[] NO If CSF is not attached complete Item A through C.

A. INFORMATION REQUIRED:

% Check Applicable Category

[ ] Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).
[x] Provide PCC for Non-Food Use inert Ingredient (s).
[ ] Provide PCC for Active Ingredient (s).
[ ] Provide PCC for Dye.
[ ] Determine if Fragrance is Acceptable for Use In Formulation.
[ ] *Other (Describe):*_____

B. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No/File Symbol **39967-71**	Product Name: **Preventol A 14-D**
Registrant: **Lanxess Corporation**	Food-Use Pesticide: [] Yes [x] No
Percent in Formulation (For Fragrance (% /Dyes %)	

C. INGREDIENT INFORMATION:

Ingredient No.1

INFORMATION REPORTED:

Chem. Name:	**PCC:** [redacted]
Trade Name: [redacted]	TOL. STATUS:
CAS Reg. No.: [redacted]	OTHER INF.:

Ingredient No.2:

Chem. Name:	**PCC:**
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.3

Chem. Name:	**PCC:**
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.4:

Chem. Name:	**PCC:**
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Approved By: A. Dohesai
Dated approved: 7.25.13

Inert ingredient information may be entitled to confidential treatment

CHEMICAL ME/PESTICIDE CHEMICAL ODE (PCC) REQUEST FORM

CR# _____

REQUESTOR NAME: Juan F. Negrón			Request date: 07/23/13
Tel: 703-308-8116	ORG.: AD	ROOM: 8848	MAIL CODE: 7510P

CSF ATTACHED:
[x] YES If CSF is attached complete Item A and the chemical name in item C.
[] NO If CSF is not attached complete Item A through C.

A. INFORMATION REQUIRED:

% Check Applicable Category

[ ] Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).
[x] Provide PCC for Non-Food Use inert Ingredient (s).
[ ] Provide PCC for Active Ingredient (s).
[ ] Provide PCC for Dye.
[ ] Determine if Fragrance is Acceptable for Use In Formulation.
[ ] *Other (Describe):* _____

B. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No/File Symbol **39967-71**	Product Name: **Preventol A 14-D**
Registrant: **Lanxess Corporation**	Food-Use Pesticide: [] Yes [x] No
Percent in Formulation (For Fragrance (**%** /Dyes **%**)	

C. INGREDIENT INFORMATION:

Ingredient No.1

INFORMATION REPORTED:

Chem. Name:	**PCC:**
Trade Name: [redacted]	TOL. STATUS:
CAS Reg. No. [redacted]	OTHER INF.:

Ingredient No.2:

Chem. Name:	**PCC:**
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.3

Chem. Name:	**PCC:**
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.4:

Chem. Name:	**PCC:**
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Approved By: _____
Dated approved: _____

Inert ingredient information may be entitled to confidential treatment

Decision #: 480625
DP #: (412935)
NON PRIA
Parent DP #:
Submission #: 936248
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 03-Jul-2013

* * * Registration Information * * *

Registration: 39967-71 - PREVENTOL A 14-D

Company: 39967 - LANXESS CORPORATION

Risk Manager:

Risk Manager Reviewer: Stacey Grigsby SGRIGSBY

Sent Date: PRIA Due Date: 01-Sep-2013 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients: See page 2

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 03-Jul-2013 Due Back:

DP Ingredient: See page 2

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

	Assigned To	Date In	Date Out	
Organization:	AD / PSB			Last Possible Science Due Date: 18-Jul-2013
Team Name:	CTT			Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Minor Formulation Change

Please review alternates 4-11. Registrant is changing source of active and modigying inert ingredients

Decision #: 480625
DP #: (412935)
NON PRIA
Parent DP #:
Submission #: 936248
E-Sub #:

DATA PACKAGE BEAN SHEET

Date: 03-Jul-2013

* * * Registration Information * * *

Registration: 39967-71 - PREVENTOL A 14-D

Company: 39967 - LANXESS CORPORATION

Risk Manager:

Risk Manager Reviewer: Stacey Grigsby SGRIGSBY

Sent Date: PRIA Due Date: 01-Sep-2013 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients: See page 2

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 03-Jul-2013 Due Back:

DP Ingredient: See page 2

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To	Date In	Date Out	
Organization: AD / PSB			Last Possible Science Due Date: ~~13-Jul-2013~~ August 18, 2013
Team Name: CTT			Science Due Date: 7/9/13
Reviewer Name: Sean	7/3/13	7/23/13	Sub Data Package Due Date: 7/19/13
Contractor Name:			

TFN 02 JC

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Minor Formulation Change

Please review alternates 4-11. Registrant is changing source of active and modigying inert ingredients

JC

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

JUL - 2 2013

Ms. Luanne Jeram
LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, Pennsylvania 15275-1112

Subject: **Amended Reregistration Label**
PREVENTOL A 14-D
EPA Registration Number 39967-71
EPA Decision Number 433417

Dear Ms. Jeram,

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all of the information submitted with your application to support the reregistration of the above referenced product in connection with the Octhilinone and Diuron REDs, and has concluded that your submission is acceptable.

NOTE: This product is **not** being reregistered under sections 3(c)5 and 4(g) of FIFRA at this time.

Please note that the record for this product currently contains the Confidential Statements of Formulation (CSFs) listed below. Any previously dated CSFs are superseded.

- Basic CSF, dated January 14, 2011
- Alternate CSF #1, dated January 14, 2011
- Alternate CSF #2, dated January 14, 2011
- Alternate CSF #3, dated January 14, 2011

A copy of your label stamped "Accepted" is enclosed along with copies of the acute toxicity and product chemistry reviews completed for the subject product. Products shipped after 12 months from the date of this amendment or the next printing of the label whichever occurs first, must bear the new revised label. Your release for shipment of the product bearing the amended label constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e).

If you have any questions about this letter, please contact Seiichi Murasaki at murasaki.seiichi@epa.gov.

Sincerely,

Jacqueline Campbell-Hardy
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosures: *Label stamped "Accepted," dated July 2, 2013*
Acute Toxicity Review, dated November 23, 2011.

PREVENTOL® A14-D

TO INHIBIT THE GROWTH OF FUNGI AND ALGAE IN PAINTS, COATINGS, PLASTERS, STUCCO, SEALANTS, CAULKS AND FILLERS

JUL - 2 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.

ACTIVE INGREDIENTS: 3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22%
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim)	10%
2-n-octyl-isothiazoline-3-one (NOIT; Octhilinone)	3%
INERT INGREDIENTS	65%
TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CORROSIVE. Causes irreversible eye damage and skin burns. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor and mist, avoid skin contact. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders and other handlers must wear: Protective eye wear (goggles) or a face shield, long-sleeved shirt and long pants, socks, shoes, chemical resistant gloves (from water-proof material), chemical resistant apron and NIOSH approved respirator with an organic vapor (OV) cartridge with any N, R, P or HE pre-filter. Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE seperately from other laundry. Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them.

USER SAFETY INSTRUCTIONS

Users must wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Users must remove clothing / PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Users must remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and changes into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Do not contaminate water when disposing of equipment wash waters. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300
INTERNATIONAL 703-527-3887

EPA Reg. No.: 39967-71
EPA Est. No.:

FIRST AID

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a Poison Control center or doctor or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063

Net Contents:
Lot No.:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.

FOR DETAILED DIRECTIONS FOR USE, PLEASE REFER TO THE LANXESS CORPORATION LABEL SUPPLEMENTS. Read entire Directions before using PREVENTOL® A14-D.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Product should be stored in an area that is not subject to extreme temperatures. Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If the container is leaking material for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed below.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or re this container. Offer for recycling if available or reconditioning if appropr.

METAL CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PLASTIC CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in senitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

® Preventol is a registered trademark of LANXESS Corporation

LANXESS

LANXESS Corporation
111 RIDC Park West Drive • Pittsburgh, PA 15275-1112

LABEL TEXT DATE: 5/7/2013

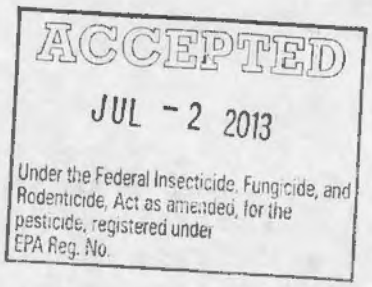
LANXESS

Energizing Chemistry

Product Information

PREVENTOL® A14-D

EPA Registration Number 39967-71



PREVENTOL® A14-D

PRESERVATIVE FOR INDUSTRIAL AND COMMERCIALUSES

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

The following guidance is given as an approximation for each use pattern, but field-testing is required to achieve optimum effectiveness. Do not apply this product in a way that will contact workers or other persons, wither directly or through drift. Only protected handlers may be in the area during application.

GENERAL USE DIRECTIONS

PREVENTOL® A14-D is an antimicrobial preservative to inhibit the growth of fungi and algae in paints, coatings, plasters, sealants and fillers used for architectural products, finishes and special purpose coatings. Typical use levels that are given for the various applications indicate the approximate levels for the particular application. All use levels are in percentage by weight and refer to the product PREVENTOL® A14-D. In order to determine the most cost effective use level in a given use, field trials are suggested.

PAINTS AND COATINGS:
PREVENTOL® A14-D provides control of fungi and algae in paints and coatings, when used as an in container preservative. Add 1.5 to 20 lbs (0.68 to 9.1 kg) of PREVENTOL® A14-D to each 1000 lbs (453 kg) of paint or coating material. PREVENTOL® A14-D is typically effective when applied at concentrations of 0.15% - 2.0% of finished product.
Method of Addition:
PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product to assure universal distribution.

PLASTER AND STUCCO:
PREVENTOL® A14-D provides control of fungi and algae in plaster and stucco, when used as an in container preservative. Add 1 to 10 lbs (0.45 to 4.5 kg) of PREVENTOL® A14-D to each 1000 lbs (453 kg) of plaster or stucco. PREVENTOL® A14-D is typically effective when applied at concentrations of 0.1% - 1.0% of finished product.
Method of Addition:

PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product to assure universal distribution.

SEALANTS, CAULKS AND FILLERS:
PREVENTOL® A14-D provides control of fungi and algae in sealants, caulks and fillers, when used as an in container preservative. Add 1 to 15 lbs (0.45 to 6.8 kg) of PREVENTOL® A14-D to each 1000 lbs (453 kg) of sealant, caulk and filler. PREVENTOL® A14-D is typically effective when applied at concentrations of 0.1% - 1.5% of finished product.

Method of Addition:
PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product to assure universal distribution.

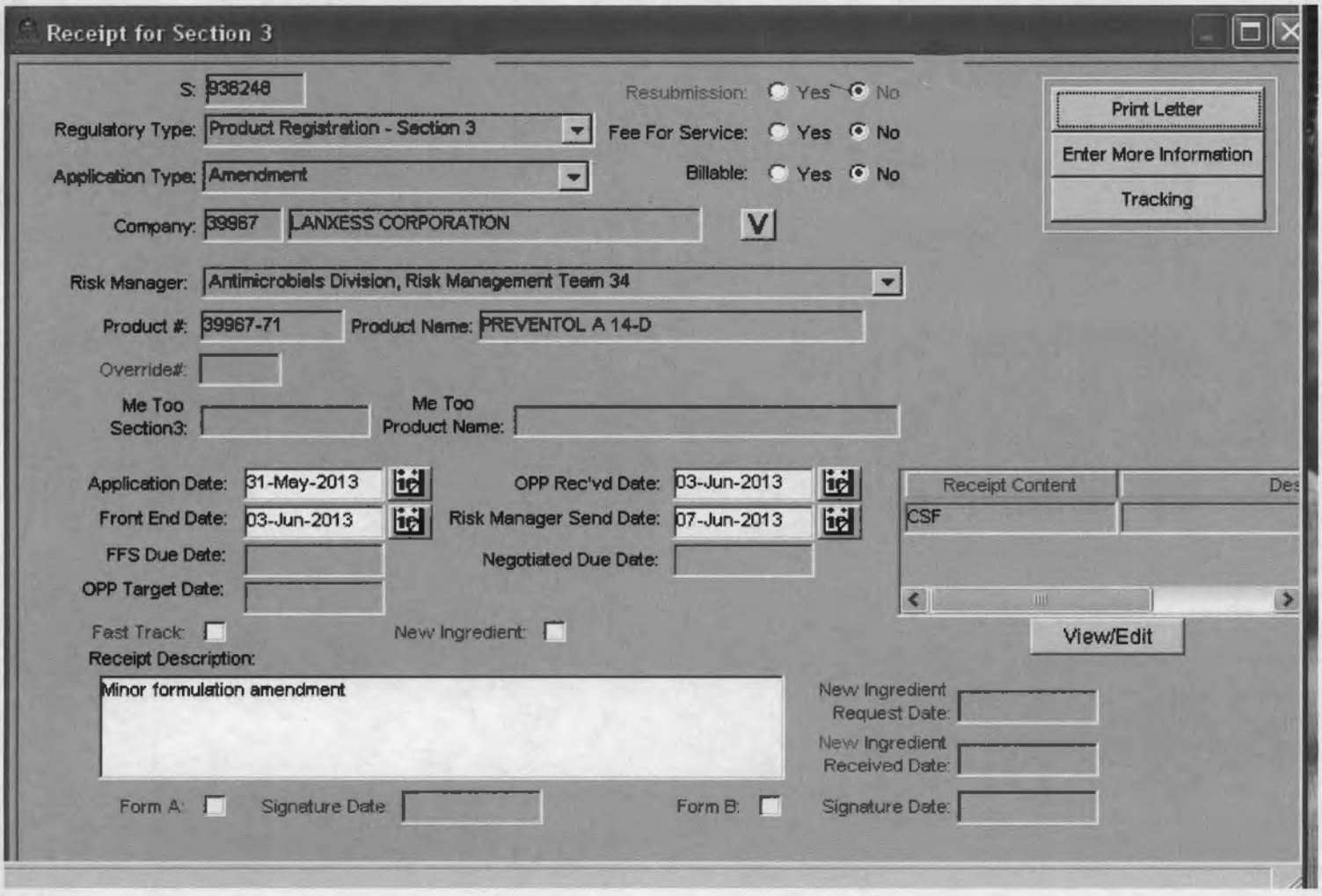
REMARKS
If you need assistance or information, please call your nearest LANXESS representative, or our Pittsburgh office at 800-LANXESS.

IN CASE OF EMERGENCY, CALL: CHEMTREC 1-800-424-9300
INTERNATIONAL (703)-527-3887

HAVE THE PRODUCT CONTAINER OF LABEL WITH YOU WHEN CALLING A POISON CONTROL CENTER OR DOCTOR OR GOING FOR TREATMENT.

LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275
412-809-1000

5/13


Receipt for Section 3
S: 936248
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: Amendment
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 39967 LANXESS CORPORATION
Risk Manager: Antimicrobials Division, Risk Management Team 34
Product #: 39967-71
Product Name: PREVENTOL A 14-D
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 31-May-2013
OPP Rec'vd Date: 03-Jun-2013
Front End Date: 03-Jun-2013
Risk Manager Send Date: 07-Jun-2013
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
Minor formulation amendment
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNI. _J STATES ENVIRONMENTAL PROTEC J AGENCY
WASHINGTON, D.C. 20460

June 7, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LUANNE JERAM
LANXESS CORPORATION
111 RIDC PARK WEST DRIVE
PITTSBURGH, PA 15275-1112

PRODUCT NAME: PREVENTOL A 14-D
COMPANY NAME: LANXESS CORPORATION
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 39967-71
EPA RECEIPT DATE: 06/03/13

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Antimicrobials Division, Risk Management Team 34, at {703-308-6416}.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {936248A~

This package includes the following

- ○ New Registration
- ◉ Amendment

□ Studies? □ Fee Waiver?

□ volpay % Reduction: ___

for Division

- ◉ AD
- ○ BPPD
- ○ RD

Risk Mgr. 34

Receipt No. S-	936248
EPA File Symbol/Reg. No.	39967-71
Pin-Punch Date:	6/3/2013

☒ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

▣ Inert Cleared for Intended Use ▣ Uncleared Inert in Product

Reviewer: Team 2 Date: 6/6/13

Remarks:

DATA PACKAGE BEAN SHEET

Date: 03-Jul-2013

Decision #: 480625
DP #: (412935)
NON PRIA
Parent DP #:
Submission #: 936248
E-Sub #:

* * * Registration Information * * *

Registration: 39967-71 - PREVENTOL A 14-D

Company: 39967 - LANXESS CORPORATION

Risk Manager:

Risk Manager Reviewer: Stacey Grigsby SGRIGSBY

Sent Date: PRIA Due Date: 01-Sep-2013 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients: See page 2

* * * Data Package Information * * *

Expedite: ● Yes ○ No Date Sent: 03-Jul-2013 Due Back:

DP Ingredient: See page 2

DP Title: Product Chemistry

CSF Included: ● Yes ○ No Label Included: ● Yes ○ No Parent DP #:

Assigned To	Date In	Date Out
Organization: AD / PSB		
Team Name: CTT		
Reviewer Name:		
Contractor Name:		

8/18/2013 se

Last Possible Science Due Date: ~~18-Jul-2013~~

Science Due Date:

Sub Data Package Due Date:

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Minor Formulation Change

Please review alternates 4-11. Registrant is changing source of active and modigying inert ingredients

Pages 45-52 Inert & product ingredient source information may be entitled to confidential treatment

Date: December 28, 2011

Reg. No.: 39967-71
Product Name: Preventol® A14-D
PM Name/Number: Campbell-McFarlane, AD Risk Management Team 34

Primary Reviewer: Shirley Keel
Secondary Reviewer: Mark Perry

New label or date of RD amended label: Received on 1/18/11

Formulation Type: Emulsifiable Concentrate

Active Ingredient Assessed: Octhilinone/099901, Diuron/035505

Other ai's in product

Name/PC code:	Reregistration Status or Registration Date:
Carbendazim/128872	Registered on 9/8/93

Assessment can be found in N:\RMIB V\label\039967/71

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1) This product has been classified as a Restricted Use Pesticide due to eye and skin irritation. Add the following text to the top of the front panel of the label, preferably enclosed in a box:

> Restricted Use Pesticide
>
> Due to **eye and skin irritation**
>
> For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

The above text must be set in type of the same minimum size as required for human hazard signal words and appear with sufficient prominence relative to the other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use.

2) Add "Restricted Use Pesticide" immediately below the heading "Directions For Use."

3) The text in **bold type** below must be added to the following First Aid statements.

IF SWALLOWED:
Call a poison control center or doctor immediately for treatment advice.

Have person sip a glass of water if able to swallow.
Do not induce vomiting unless told to by a poison control center or doctor.
Do not give anything by mouth to an unconscious person.

IF IN EYES:
Hold eye open and rinse slowly and gently with water for 15-20 minutes.
Remove contact lenses, if present, after the first 5 minutes, then continue rinsing **eyes**.
Call a poison control center or doctor for treatment advice.

4) Per the acute toxicity review and PR Notice 2001-1, the emergency medical treatment information must be revised to read:

"Have the product **container or label** with you when calling a poison control center or doctor or going for treatment."

5) The Agency recommends that additional text be added to the Note to Physician that addresses the Toxicity Category I primary eye and dermal irritation concerns. The following statements are some suggested type of information that could be included, if applicable, in the Note to Physicians:

-technical information on symptomatology;
-use of supportive treatments to maintain life functions;
-medicine that will counteract the specific physiological effects of the pesticides;
-company telephone number to specific medical personnel who can provide specialized medical advice.

6) Per the Ochthilinone and Diuron REDs, the PPE text currently under Hazards to Humans and Domestic Animals section must be revised to read:

Mixers, loaders, applicators, and other handlers must wear:

-Long-sleeved shirt and long pants,
-Shoes plus socks,
-Goggles or face shield,
-Chemical-resistant gloves (such as those made from natural rubber),
-Chemical –resistant apron worn over long sleeved shirt and long pants and a NIOSH approved respirator with an organic vapor (OV) cartridge or canister with any N, R, P or HE pre-filter.

7) Per the Label Review Manual, User Safety Requirements text must be added to the label:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

8) Per the Diuron RED and the acute toxicity review, User Safety Recommendations must be added to the label and placed in a box:

"User Safety Recommendations

User should wash hands before, eating, drinking, chewing gum, using tobacco, or **using the toilet**.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

9) Per the Diuron RED, the following text must be added to the Environmental Hazards section of the label:

"Do not contaminate water when disposing of equipment wash waters."

10) Per the Diuron RED, the following application restrictions must appear under the heading Directions for Use:

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

11) Add the product's "**EPA Registration Number: 39967-71**" to the label.

1XR 4001774

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 23, 2011

MEMORANDUM:

Subject: EPA Reg. No.: 39967-71/ Preventol A14-D
DP Barcode: 395808
Case No.: 2475

From: Sergey Alekseyev, Chemist SA
Risk Management and Implementation Branch V (7508P)
Pesticide Re-evaluation Division

To: Maia Tatinclaux, CRM MJP
Risk Management and Implementation Branch V (7508P)
Pesticide Re-evaluation Division

Applicant: LANXESS Corporation
111 RIDC Park West Drive, Pittsburgh, PA 15275-1112

FORMULATION FROM EPA Reg. No. 39967-71 LABEL:

	% by wt.
Active Ingredient(s):	
Octhilinone	3.0%
Diuron	22.0%
Carbendazim	10.0%
Other Ingredient(s):	65.0%
Total	100.0%

BACKGROUND: In the 8 month response to the Octhilinone RED, the registrant submitted six (81-1, 81-2, 81-3, 81-4, 81-5, 81-6) acute toxicity studies to support the reregistration of their product. The MRID's are as follows: 473893-04 (81-1), 473083-05 (81-2), 473893-06 (81-3), 473893-07 (81-4), 473893-08 (81-5), and 473893-02 (81-6). These MRIDs have been reviewed by AD 06/05/2008 and found acceptable. PRD concurs with this review. The studies were conducted by Product Safety Labs.

RECOMMENDATIONS:

- The acute toxicity studies submitted are acceptable to support the reregistration of EPA Reg. No. 39967-71.

The acute toxicity profile for EPA Reg. No. 39967-71 is currently:

Acute Oral	III	Cited
Acute Dermal	IV	Cited
Acute Inhalation	III	Cited
Primary Eye	I	Cited
Primary Dermal	I	Cited
Skin Sensitization	Sensitizer	Cited

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 039967-00071 Preventol A14-D

RESTRICTED USE CLASSIFICATION REQUIRED

Due to Category I eye and dermal irritation.

SIGNAL WORD: **DANGER**

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Corrosive. Causes irreversible eye injury. Do not get in eyes or on clothing. Harmful if swallowed. Harmful if inhaled. Avoid breathing vapor and mist, avoid contact on skin. Wear protective eyewear (goggles, face shield, or safety glasses). Wear coveralls over long sleeved shirt, long pants, shoes, and socks. Wear chemical-resistant gloves (made of any chemical-resistant material, Category A). Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

DATE OUT: 11/15/2011

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI[ ]; MUP [ ]; EUP [X]
BARCODE NO.: 395806 **REG./FILE SYMBOL NO.:** 39967-71
PRODUCT NAME: Preventol A14-D **MRID NOS:** 473893-01, 473893-02, 473893-03, and 476729-01
COMPANY NAME: LANXESS Corporation **ACTION CODE:** 676

FROM: Sergey Alekseyev, Chemist
Product Chemistry Team
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

TO: Maia Tatinclaux, CRM
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case No. 2475, was issued on 09/28/2007 for the Active Ingredient Octhilinone a.k.a. OIT a.k.a. NOIT a.k.a. Kathon. According to the RED, the generic database supporting the reregistration of Octhilinone for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Octhilinone RED, LANXESS Corporation provided EPA Form 8570-35 (Data Matrix), dated 1/14/2011; EPA Form 8570-4 (Confidential Statement of Formula), one basic and three alternative formulations, dated 1/14/2011; a draft label, punch date 01/18/2011; and MRID Nos. 473893-01, 473893-02, 473893-03, and 476729-01. The registrant is requesting reregistration of the product, Preventol A14-D, EPA Reg. No. **39967-71**.

FINDINGS:

1. EPA Reg. No. **39967-71** is an end-use product containing the active ingredient Octhilinone (2-Octyl-3(2H)-isothiazolone), Diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea), and Carbendazim (2-Benzimidazolecarbamic acid, methyl ester), with a label claim nominal concentration of 3%, 22%, and 10%, respectively; and inert ingredients content of 65%. The product is for use for inhibiting growth of fungi and algae in paints, coatings, plasters, stucco, sealants, caulks, and fillers. The product is produced by a non-integrated system.

2. The CSFs for all formulations are acceptable. The nominal concentration of the active ingredient agrees with that on the label, meeting PR Notice 91-2. The certified limits for the active ingredient and the inert ingredients are acceptable in accordance with 40 CFR §158.350. All ingredients are cleared for use in pesticide formulations.

3. Data reported for MRID Nos. 473893-01, 473893-02, 473893-03, and 476729-01 satisfy the product chemistry data requirements under Subgroups A and B which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

Note: all MRIDs pertains to the product EXP P108-14 which essentially the same as the subject product (see MRID No. 473893-02).

4. The Ingredients Statement on the draft label is acceptable as per CFR §156.10(g) and PR Notices 91-2 and 97-6. No data are present to trigger the need for a Physical or Chemical Hazards Statement. The Storage and Disposal Statements are acceptable in accordance with CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSIONS:

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. **39967-71.**

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	CSF	Y
.1600 Description of Materials Used to Produce the Product	158.325	474442-01	Y
.1620 Description of Production Process	158.330		N/A
.1650 Discussion of Formulation Process	158.165	474442-01	Y
.1670 Discussion of Formation of Impurities	158.167	474442-01	Y
.1700 Preliminary Analysis	158.345		N/A
.1750 Certified Limits	158.350	CSF and 474442-01	Y
.1800 Enforcement Analytical Method	158.355	474442-01	Y

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Clear	465844-01	Y
.6303 Physical State	Liquid	465844-01	Y
.6304 Odor	Slight	465844-01	Y
.6313 Stability	The product is not TGAI/MP		N/A
.6314 Oxidation/Reduction Chemical Incompatibility	The product does not contain oxidizer/reducer	474442-01	N/A
.6315 Flammability/Flame Extension	>100 °C (212 °F)	474442-02	Y
.6316 Explodability	The product is not potentially explosive	474442-01	N/A
.6317 Storage Stability	The product is stable after 1 year at RT	477043-01	Y
.6319 Miscibility	The product is not emulsifiable liquid; it will not be diluted with petroleum solvents	474442-01	N/A
.6320 Corrosion Characteristics	No signs of corrosion attack upon containers' material (HDPE)	477043-01	Y
.6321 Dielectric Breakdown Voltage	The product is not be used around electrical equipment	474442-01	N/A
.7000 pH	5.55	474442-08	Y
.7050 UV/ Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	58.196 cps at 20°C	474442-02	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.036 g/ml at 20 °C	474442-02	Y
.7370 Dissociation Constant in Water	Not applicable. The product is not TGAI/MP.		N/A
.7550 Octanol/ Water Partition Coefficient	Not applicable. The product is not TGAI/MP.		N/A
.7840 Solubility to Water and Organic Solvents	Not applicable. The product is not TGAI/MP.		N/A
.7950 Vapor Pressure	Not applicable. The product is not TGAI/MP.		N/A

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

DATE OUT: 11/15/2011

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: TGAI[ ]; MUP [ ]; EUP [X]
BARCODE NO.: 395806 **REG./FILE SYMBOL NO.:** 39967-71
PRODUCT NAME: Preventol A14-D **MRID NOS:** 473893-01, 473893-02, 473893-03, and 476729-01
COMPANY NAME: LANXESS Corporation **ACTION CODE:** 676

FROM: Sergey Alekseyev, Chemist
Product Chemistry Team
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

TO: Maia Tatinclaux, CRM
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

INTRODUCTION:

A Reregistration Eligibility Decision (RED), Case No. 2475, was issued on 09/28/2007 for the Active Ingredient Octhilinone a.k.a. OIT a.k.a. NOIT a.k.a. Kathon. According to the RED, the generic database supporting the reregistration of Octhilinone for currently registered uses has been reviewed and found to be substantially complete.

In the 8-month response to the Octhilinone RED, LANXESS Corporation provided EPA Form 8570-35 (Data Matrix), dated 1/14/2011; EPA Form 8570-4 (Confidential Statement of Formula), one basic and three alternative formulations, dated 1/14/2011; a draft label, punch date 01/18/2011; and MRID Nos. 473893-01, 473893-02, 473893-03, and 476729-01. The registrant is requesting reregistration of the product, Preventol A14-D, EPA Reg. No. **39967-71**.

FINDINGS:

1. EPA Reg. No. **39967-71** is an end-use product containing the active ingredient Octhilinone (2-Octyl-3(2H)-isothiazolone), Diuron (3-(3,4-dichlorophenyl)-1,1-dimethylurea), and Carbendazim (2-Benzimidazolecarbamic acid, methyl ester), with a label claim nominal concentration of 3%, 22%, and 10%, respectively; and inert ingredients content of 65%. The product is for use for inhibiting growth of fungi and algae in paints, coatings, plasters, stucco, sealants, caulks, and fillers. The product is produced by a non-integrated system.

2. The CSFs for all formulations are acceptable. The nominal concentration of the active ingredient agrees with that on the label, meeting PR Notice 91-2. The certified limits for the active ingredient and the inert ingredients are acceptable in accordance with 40 CFR §158.350. All ingredients are cleared for use in pesticide formulations.

3. Data reported for MRID Nos. 473893-01, 473893-02, 473893-03, and 476729-01 satisfy the product chemistry data requirements under Subgroups A and B which pertain to Product Identity and Composition, and Physical and Chemical Properties, respectively.

Note: all MRIDs pertains to the product EXP P108-14 which essentially the same as the subject product (see MRID No. 473893-02).

4. The Ingredients Statement on the draft label is acceptable as per CFR §156.10(g) and PR Notices 91-2 and 97-6. No data are present to trigger the need for a Physical or Chemical Hazards Statement. The Storage and Disposal Statements are acceptable in accordance with CFR §156.10(i)(2)(ix) and PR Notice 83-3.

CONCLUSIONS:

The registrant has satisfied the product chemistry requirements for the reregistration of EPA Reg. No. **39967-71.**

Product Chemistry Data

Subgroup A: Series 830.1550 - 830.1800 (40 CFR 158.155 - 158.180)

GUIDELINE REFERENCE NO. (GRN)/ TITLE 830	40 CFR §	MRID Number	Data Fulfilled
.1550 Product Identity and Composition	158.320	CSF	Y
.1600 Description of Materials Used to Produce the Product	158.325	474442-01	Y
.1620 Description of Production Process	158.330		N/A
.1650 Discussion of Formulation Process	158.165	474442-01	Y
.1670 Discussion of Formation of Impurities	158.167	474442-01	Y
.1700 Preliminary Analysis	158.345		N/A
.1750 Certified Limits	158.350	CSF and 474442-01	Y
.1800 Enforcement Analytical Method	158.355	474442-01	Y

Subgroup B: Series 830.6302 - 7950 (40 CFR 158.190)

Guideline Reference No. (GRN) / Title 830	Value or Qualitative Description	MRID Number	Data Fulfilled
.6302 Color	Clear	465844-01	Y
.6303 Physical State	Liquid	465844-01	Y
.6304 Odor	Slight	465844-01	Y
.6313 Stability	The product is not TGAI/MP		N/A
.6314 Oxidation/Reduction Chemical Incompatibility	The product does not contain oxidizer/reducer	474442-01	N/A
.6315 Flammability/Flame Extension	>100 °C (212 °F)	474442-02	Y
.6316 Explodability	The product is not potentially explosive	474442-01	N/A
.6317 Storage Stability	The product is stable after 1 year at RT	477043-01	Y
.6319 Miscibility	The product is not emulsifiable liquid; it will not be diluted with petroleum solvents	474442-01	N/A
.6320 Corrosion Characteristics	No signs of corrosion attack upon containers' material (HDPE)	477043-01	Y
.6321 Dielectric Breakdown Voltage	The product is not be used around electrical equipment	474442-01	N/A
.7000 pH	5.55	474442-08	Y
.7050 UV/ Visible Light Absorption	Not applicable. The product is not TGAI/MP.		N/A
.7100 Viscosity	58.196 cps at 20°C	474442-02	Y
.7200 Melting Point	Not applicable. The product is not TGAI/MP.		N/A
.7220 Boiling Point	Not applicable. The product is not TGAI/MP.		N/A
.7300 Density/Bulk Density	1.036 g/ml at 20 °C	474442-02	Y
.7370 Dissociation Constant in Water	Not applicable. The product is not TGAI/MP.		N/A
.7550 Octanol/ Water Partition Coefficient	Not applicable. The product is not TGAI/MP.		N/A
.7840 Solubility to Water and Organic Solvents	Not applicable. The product is not TGAI/MP.		N/A
.7950 Vapor Pressure	Not applicable. The product is not TGAI/MP.		N/A

Explanations: Y = Requirement fulfilled; N = Requirement not fulfilled; N/A = Not applicable; G = Data gap; U = Upgradeable; I = Incomplete or in progress; W = Waived

Pages 66-86 Inert & product ingredient source information may be entitled to confidential treatment

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company / Product Number	2. EPA Product Manager	3. Proposed Classification
39967-71	Jacqueline Campbell-McFarlane	[x] None [ ] Restricted
4. Company / Product (Name) PREVENTOL A14-D	PM# 34	
5. Name and Address of Applicant (*include ZIP Code*) LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112 [ ] *Check of this is a new address*	6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3) (b)(I) my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

[ ] Amendment - Explain Below
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application
[X] Other - Explain below

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
This is being submitted for the eight-month, product specific response for the Preventol A14-D, (case# 2475, ID# PDCI-099901-29784)

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes [X] No	[ ] Yes [X] No		[ ] Yes [X] No		[ ] Metal [X] Plastic
*** Certification must be submitted**	If "Yes" Unit Packaging wgt	No. per container	If "Yes" Package Wgt	No. per container	[ ] Glass [ ] Paper [ ] Other (Specify)

3. Location of Net Contents Information	4. Size(s) retail Container	5. Location of Label Directions
[ ] Label [X] Container	55 gallon	on container

6. Manner in Which Label is affixed to Product: [ ] Lithograph [X] Paper glues [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application.)

Name	Title	Telephone No. (Include Area Code)
Stan Oslosky	Manager Regulatory Affairs	412-809-3577 / 412-809-1082(fax)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature	3. Title	6. Date Application Received (Stamped)
[signature]	Manager Regulatory Affairs	
4. Typed Name: Stan Oslosky	5. Date: 14-Jan-11	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Form Approved OMB No. 2070-0060

United States Environmental Protection Agency
Washington, D.C. 20460

EPA

Formulator's Exemption Statement

(40 CFR 152-85)

Applicant's Name and Address	EPA File Symbol/Registration Number
LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112	**39967-71**
	Product Name **Preventol A14-D**
	Date of Confidential Statement of Formula *(EPA form 8570-4)* **January 14, 2011**

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

Diuron

Carbendazim

2-n-Octyl-4-isothiazolin-3-one (NOIT)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA Form 8570-4)* for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula *(CSF) (EPA Form 8570-4)* referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source Product Name	Source Registration Number
Diuron	[redacted]	
Carbendazim		
2-n-Octyl-4-isothiazolin-3-one (NOIT)		

Signature	Name and Title	Date
	Stan Oslosky/ MgrRegulatory Affairs	**January 14, 2011**

EPA Form 8570-27 (Rev. 7-91) White – EPA copy Yellow – Applicant Copy

Product Source information May be Entitled to Confidential Treatment

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number/File Symbol:
LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112, 412-809-3709	**39967- 71**
Active Ingredient(s) and/or representative test compound(s): Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)	Date: **January 14, 2011**
General Use Pattern(s): **Indoor**	Product Name: **Preventol A14-D**

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

I am using the cite-all method of support, and have included with this form a list of companies sent offer of compensation (the Data Matrix form should be used for this purpose).	X	I am using the selective method of support (or the cite-all option under the selective method), and have included with the forms a completed list of data requirements (the Data Matrix must be used).

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]]

X I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commenca negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(8) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Stan P Oslosky	**January 14, 2011**	Stan Oslosky, Manager, Regulatory Affairs

EPA Form 8570-36 (9-97) Electronic and Paper versions available. Submit only Paper version

LANXESS
Energizing Chemistry

Document Processing Desk (DCI/PRD)
Moana Appleyard
Office of Pesticide Programs (7508P)
U.S. Environmental Protection Agency
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive
Arlington, VA 22202

COURIER ONLY

January 14, 2011
Stan Oslosky
Product Safety and Regulatory Affairs
111 Park West Drive
Pittsburgh, PA 15272-1112
Phone 412-809-3577
Fax 412-809-1056
stan.oslosky@lanxess.com
www.US.LANXESS.com

Subject: Reregistration Case #: 2475: Octhilinone
PDCI-099901-29784

Dear Ms. Appleyard:

This eight month response is being sent by LANXESS Corporation. These products are registered under the company number 39967.

Enclosed in this response are the following:

1. **Preventol A14-D (39967-71)**
-Form 8570-1 Reregistration application
-Form 8570-4 Confidential statement of formula, one basic three alternate (2 copies)
-Form 8570-27 Formulator Exemption Statement
-Form 8570-34 Certification With Respect to Data Citation
-Form 8570-35 Data Matrix, 3pp
-Form 8570-35 Data Matrix (Masked copy)
-Product labeling (5 copies)

2. **Preventol A17-D (39967-65)**
-Form 8570-1 Reregistration application
-Form 8570-4 Confidential statement of formula, one basic one alternate (2 copies)
-Form 8570-27 Formulator Exemption Statement
-Form 8570-34 Certification With Respect to Data Citation
-Form 8570-35 Data Matrix, 3pp
-Form 8570-35 Data Matrix (Masked copy)
-Product labeling (5 copies)

3. **Preventol S600-L (39967-73)**
-Form 8570-1 Reregistration application
-Form 8570-4 Confidential statement of formula, one basic (2 copies)
-Form 8570-27 Formulator Exemption Statement
-Form 8570-34 Certification With Respect to Data Citation
-Form 8570-35 Data Matrix, 3pp
-Form 8570-35 Data Matrix (Masked copy)
-Product labeling (5 copies)

4. **Preventol CT-L (39967-46)**
-LANXESS wishes to cancel this product voluntarily and hereby waives the 180-day period. The maintenance fee were not paid for 2011

If you have any question concerning this response, please let me know.

Sincerely,

Stan Oslosky
Principal HES

Form Approved OMB No. 2070-0060

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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date January 14, 2011	EPA Reg. No./File Symbol 39967- 71	Page 1 of 3
licant's/Registrant's Name & Address XESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	

Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PRODUCT CHEMISTY				
830.1550	Product identity and composition	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1600	Description of starting materials	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1620	Description of production process	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1650	Description of formulation process	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1670	Discussion of formation of impurities	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1700	Preliminary Analysis of Product	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1750	Certified Limits	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1800	Enforcement Analytical methods	47389301	39967 (Submitted on 3/27/2008)	OWN	VOLUME 9
830.1900	Submittal of Samples	Not applicable	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6302	Color - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.6302	Color – EP	47389303	39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.6303	Physical state - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.6303	Physical state - EP	47389303	39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.6304	Odor - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	

Signature	Name and Title	Date
Stacy C Oslosky	Stan Oslosky, Manager Regulatory Affairs	January 14, 2011

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DATA MATRIX

Date January 14, 2011	EPA Reg. No./File Symbol 39967- 71	Page 2 of 3
icant's/Registrant's Name & Address NXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	

Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PRODUCT CHEMISTY – Continued				
830.6304	Odor – EP	47389303	39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.6313	Stability - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.6314	Oxidizing or reducing action	47389302	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6315	Flammability	47389302	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6316	Explodability	47389302	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
830.6317	Storage stability	47672901	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
830.6319	Miscibility	47389302	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6320	Corrosion Characteristics	47672901	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
830.6321	Dielectric breakdown voltage	47389302	39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.7000	pH - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7000	pH - EP	47389303	39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.7100	Viscosity	47389303	39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.7200	Melting Point – TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7220	Boiling Point - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	

Signature	Name and Title	Date
Stan Oslosky	Stan Oslosky, Manager Regulatory Affairs	January 14, 2011

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DATA MATRIX

January 14, 2011	EPA Reg. No./File Symbol 39967- 71	Page 3 of 3
Applicant's/Registrant's Name & Address LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	

Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7300	Density – EP	47389303	39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.7370	Dissociation constant - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7550	Octanol/water partition coefficient - PAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7840	Solubility – TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7950	Vapor Pressure - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
	ACUTE TOXICOLOGY				
870.1100	Acute oral LD-50,rat	47389304	39967	OWN	VOLUME 4
870.1200	Acute dermal LD-50	47389305	39967	OWN	VOLUME 5
870.1300	Acute inhalation LC-50,rat	47389306	39967	OWN	VOLUME 6
870.2400	Primary eye irritation rabbit	47389302	39967	OWN	VOLUME 2 (waiver)
870.2500	Primary dermal irritation	47389307	39967	OWN	VOLUME 7
870.2600	Skin sensitization	47389308	39967	OWN	VOLUME 8

Signature	Name and Title	Date
Stan Oslosky	Stan Oslosky. Manager Regulatory Affairs	January 14. 2011

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DATA MATRIX

Date January 14, 2011	EPA Reg. No./File Symbol 39967- 71	Page 1 of 3
Applicant's/Registrant's Name & Address LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	

Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PRODUCT CHEMISTY				
[redacted]			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 9
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
			Not applicable (Formulator's Exemption)	FOR	
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
			Not applicable (Formulator's Exemption)	FOR	
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
			Not applicable (Formulator's Exemption)	FOR	

Signature	Name and Title	Date
Stan Oslosky	Stan Oslosky, Manager Regulatory Affairs	January 14, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registrations and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.
Do not send the completed form to this address.

DATA MATRIX

Date January 14, 2011	EPA Reg. No./File Symbol 39967- 71	Page 2 of 3
Applicant's/Registrant's Name & Address LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	

Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PRODUCT CHEMISTY – Continued				
[redacted]			39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
			Not applicable (Formulator's Exemption)	FOR	
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
			Not applicable (Formulator's Exemption)	FOR	
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
			Not applicable (Formulator's Exemption)	FOR	
			Not applicable (Formulator's Exemption)	FOR	

Signature	Name and Title	Date
Stan Oslosky	Stan Oslosky, Manager Regulatory Affairs	January 14, 2011

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DATA MATRIX

ate January 14, 2011	EPA Reg. No./File Symbol 39967- 71	Page 3 of 3
Applicant's/Registrant's Name & Address LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	
Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]			Not applicable (Formulator's Exemption)	FOR	
			39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
			Not applicable (Formulator's Exemption)	FOR	
			Not applicable (Formulator's Exemption)	FOR	
			Not applicable (Formulator's Exemption)	FOR	
			Not applicable (Formulator's Exemption)	FOR	
			39967	OWN	VOLUME 4
			39967	OWN	VOLUME 5
			39967	OWN	VOLUME 6
			39967	OWN	VOLUME 2 (waiver)
			39967	OWN	VOLUME 7
			39967	OWN	VOLUME 8

Signature	Name and Title	Date
Stan Oslosky	Stan Oslosky, Manager Regulatory Affairs	January 14, 2011

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

✓ B-340

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

DATA CALL-IN RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 152751112	2475 Octhilinone Chemical # and Name 099901 Octhilinone	12-May-2010 PRODUCT SPECIFIC ID # PDCI-099901-29784

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
39967-46		N.A.	N.A.		Yes
39967-65		N.A.	N.A.		Yes
39967-71		N.A.	N.A.		Yes
39967-73		N.A.	N.A.		Yes

8. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative Stacy A. Ashley Manager MPP Regulatory

9. Date July 30, 2010

10. Name of Company LANXESS Corporation

11. Phone Number 412-809-3577

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 152751112	2475 Octhilinone EPA Reg. No. 39967-71	12-May-2010 PRODUCT SPECIFIC ID # PDCI-099901-29784

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
	Product Chemistry Data Requirements (Antimicrobial)								
830.1550	Product Identity and composition (52)					BB, Y, X	EP; MP; TGAI	8	6
830.1600	Description of materials used to produce the product (27)					BB, Y, X	EP; MP; TGAI	8	6
830.1620	Description of production process (28)					BB, Y, X	TGAI	8	
830.1650	Description of formulation process (29)					BB, Y, X	MP, EP	8	6
830.1670	Discussion of formation of impurities (30)					BB, Y, X	EP; MP; TGAI	8	6
830.1700	Preliminary analysis (31 ,33 ,34)					BB, Y, X	TGAI	8	
830.1750	Certified limits (32)					BB, Y, X	EP; MP; TGAI	8	6
830.1800	Enforcement analytical method (35)					BB, Y, X	EP; MP; TGAI	8	6
830.6302	Color (14)					BB, Y, X	EP; MP; TGAI	8	6
830.6303	Physical state (57)					BB, Y, X	EP; MP; TGAI	8	6
830.6304	Odor (16)					BB, Y, X	EP; MP; TGAI	8	6

10. Certification I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law

Signature and Title of Company's Authorized Representative Mgr. Regulatory Affairs

11. Date 7/30/10

12. Name of Company LANXESS Corporation

13. Phone Number (412) 809-3577

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 152751112	2475 Octhilinone EPA Reg. No. 39967-71	12-May-2010 PRODUCT SPECIFIC ID # PDCI-099901-29784

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.6313	Stability to sunlight, normal and elevated temperatures, metals, and metal ions	(7 ,8 ,53)					BB, Y, X	TGAI	8	
830.6314	Oxidizing or reducing action	(9)					BB, Y, X	MP, EP	8	8
830.6315	Flammability	(10)					BB, Y, X	MP, EP	8	6
830.6316	Explodability	(11)					BB, Y, X	MP, EP	8	8
830.6317	Storage stability of product	(36)					BB, Y, X	MP, EP	16	6
830.6319	Miscibility	(13)					BB, Y, X	MP, EP	8	8
830.6320	Corrosion characteristics	(54)					BB, Y, X	MP, EP	16	6
830.6321	Dielectric breakdown voltage	(15)					BB, Y, X	MP, EP	8	8
830.7000	pH of water solutions or suspensions	(5 ,6)					BB, Y, X	EP; MP; TGAI	8	6
830.7050	UV/Visible absorption						BB, Y, X	TGAI/PAI	8	
830.7100	Viscosity	(12)					BB, Y, X	MP, EP	8	6
830.7200	Melting point/melting range	(17 ,18)					BB, Y, X	TGAI	8	

Initial to indicate certification as to information on this page (full text of certification is on page one). AD

Date 7/30/10

United States Environmental Protection Agency Washington, D.C. 20460

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 152751112	2475 Octhilinone EPA Reg. No. 39967-71	12-May-2010 PRODUCT SPECIFIC ID # PDCI-099901-29784

4. Guideline Requirement Number	5. Study Title		PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
830.7220	Boiling point/boiling range	(19 ,20)					BB, Y, X	TGAI	8	
830.7300	Density/relative density	(21 ,22)					BB, Y, X	EP; MP; TGAI	8	6
830.7370	Dissociation constant in water	(1 ,2)					BB, Y, X	TGAI/PAI	8	
830.7550	Partition coefficient (n-octanol/water), shake flask method	(3)					BB, Y, X	TGAI/PAI	8	
830.7570	Partition coefficient (n-octanol/water), estimation by liquid chromatography	(4)					BB, Y, X	TGAI/PAI	8	
830.7840	Water solubility: Column elution method, shake flask method	(23)					BB, Y, X	TGAI/PAI	8	
830.7860	Water solubility, generator column method	(24)					BB, Y, X	TGAI/PAI	8	
830.7950	Vapor pressure	(25 ,26)					BB, Y, X	TGAI/PAI	8	
	<u>Toxicology Data Requirements (Antimicrobial)</u>									
870.1100	Acute Oral Toxicity (do not select)	(50 ,51 ,55)					BB, Y, X	EP; MP; TGAI	8	6
870.1200	Acute dermal toxicity	(37 ,38 ,39 ,56)					BB, Y, X	EP; MP; TGAI	8	6
870.1300	Acute inhalation toxicity	(46 ,47 ,48 ,49)					BB, Y, X	EP; MP; TGAI	8	6

Initial to indicate certification as to information on this page (full text of certification is on page one). LCC

Date 7/30/10

United States Environmental Protection Agency Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174

OMB Approval 2070-0107
OMB Approval 2070-0057

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address	2. Case # and Name	3. Date and Type of DCI and Number
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 152751112	2475 Octhilinone EPA Reg. No. 39967-71	12-May-2010 PRODUCT SPECIFIC ID # PDCI-099901-29784

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
870.2500	Acute dermal irritation (40 ,41 ,42 ,43)					BB, Y, X	EP; MP; TGAI	8	6
870.2600	Skin sensitization (44 ,45)					BB, Y, X	EP; MP; TGAI	8	6
870.2400	Acute eye irritation					BB, Y, X	EP; MP; TGAI	8	7

Initial to indicate certification as to information on this page (full text of certification is on page one). SLL

Date 9/30/10

Acute Toxicity Bridging Request

Preventol A-14D
EPA Reg. # 39967-71
From Volume 2 of the registration application
MRID# 47389302

870.2400 Primary Eye Irritation – WAIVER REQUEST

We are requesting to waiver the Primary Eye Irritation testing due to the severity of results in the dermal irritation study. The dermal irritation testing showed that the product is corrosive to the skin. We have chosen not to conduct the eye irritation testing and consider Preventol A14-D to be corrosive to the eye with Toxicity Category I. Preventol A14-D meets the condition specified in CFR 158.190, footnote 2 therefore a waiver is requested.

Footnote 2

([2]) Not required if test material is corrosive to skin or has a pH less than 2 or greater than 11.5; such a product will be classified toxicity category I on the basis of potential eye and dermal irritation study.

LANXESS
Energizing Chemistry

Document Processing Desk (DCI-SRRD-CRM-2475)
Moana R. Appleyard
Office of Pesticide Programs (7508P)
U. S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

August 11, 2010
Stan Oslosky
Regulatory Affairs
Material Protection
Products
111 Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3577
Fax 412-809-1068

stan.oslosky@lanxess.com
www.US.LANXESS.com

RE: **Chemical # 2475 Octhilinone**

Dear Moana,

The 90-day response for the above referenced chemical was submitted to you last week. We discover subsequently that we had omitted the footnote waiver justification. They are enclosed. The Specifc products covered are:

2475 Octhilinone
39967-46 Preventol CT-L
39967-65 Preventol A17-D
33367-71 Preventol A14-D
39967-73 Preventol S600-L

Please do not hesitate to contact me if any further information is needed or if there are any questions.

Sincerely,

Stan Oslosky
Manager, Regulatory Affairs

8/12/10

LANXESS
Energizing Chemistry

Document Processing Desk (DCI-SRRD-CRM-2475)
Moana R. Appleyard
Office of Pesticide Programs (7508P)
U. S. Environmental Protection Agency
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202

July 30, 2010
Stan Oslosky
Regulatory Affairs
Material Protection
Products
111 Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3577
Fax 412-809-1068

stan.oslosky@lanxess.com
www.US.LANXESS.com

RE: Product Specific Data-Call-In, Registrants 90-day response
2475 Octhilinone
39967-46 Preventol CT-L
39967-65 Preventol A17-D
33367-71 Preventol A14-D
39967-73 Preventol S600-L

Enclosed is the data-call-in 90-day response for the above products.

Please do not hesitate to contact me if any further information is needed or if there are any questions.

Sincerely,

Stan Oslosky
Manager, Regulatory Affairs

Chemistry Waiver Request
Preventol A-14D
EPA Reg. # 39967-71

830.1900 Submittal of samples

This data is "Conditionally Required". Samples are available upon request.

830.6314 Oxidizing or Reducing Action

This data is "Conditionally Required". Preventol A14-D does not meet the condition specified in CFR 158.190, footnote 9. Preventol A14-D contains no oxidizing or reducing agents.

Footnote 9

([9])Required if product contains an oxidizing or reducing agent

830.6315 Flammability

This data is "Conditionally Required". Preventol A14-D does not meet the condition specified in CFR 158.190, footnote 10. Preventol A14-D does not contain combustible liquids.

Footnote 10

([10])Required if product contains combustible liquids.

830.6316 Explodability - WAIVER REQUEST

Preventol A14-D contains no potentially explosive agents. A waiver based on CFR 158.190, footnote 11, is requested.

Footnote 11

([11])Required if product is potentially explosive.

830.6319 Miscibility

This data is "Conditionally Required". Preventol A14-D does not meet the condition specified in CFR 158.190, footnote 13. Preventol A14-D is not is an emulsifiable liquid and it will not be diluted with petroleum solvents.

Footnote 13

([13])Required if product is a emulsifiable liquid and is to be diluted with petroleum solvents.

830.6321 Dielectric Breakdown

This data is "Conditionally Required". Preventol A14-D does not meet the condition specified in CFR 158.190, footnote 15. Preventol A14-D is not designed for application that will require use around electrical equipment.

Footnote 15

([15])Required if end-use product is a liquid and is to be used around electrical equipment.

Material to be added to an e-Jacket/Jacke

Reg. No. 39967-71

1. ☐ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

_____

_____

2. ☒ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☒ **Notification**
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Killian Swift

Phone: _____ **Division:** AD

Date: 1/14/10

Created July 21/20(

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TASK ASSIGNMENT FORM

Antim. bial Division/Regulatory Managemer. anches I/II

A	Completed by Product Manager

PRODUCT REVIEWER: Killian Swift	**RMB I I TEAM 34**
Description of Action: Notification	**EPA File Symbol/Reg No.: 39967-71**

FQPA Action Code: 332	**Non-FQPA Action Code:** _____	**Fee for Service Action Code:** _____
Decision No. 425235	**Submission No.** 864551	**Fee for Service Fee: $** _____

	MONTH	DAY	YEAR
APPLICATION DATE	12	15	2009
EPA PIN DATE	12	16	2009
REVIEWER ASSIGNED DATE	12	24	2009
DATE DUE TO PM			2009
DATE DUE OUT OF AGENCY			2009

Type of Data:	Product Chemistry	Acute Toxicology ☐	Efficacy ☐	Environmental Fate ☐	Ecological Effects ☐	Chronic Toxicology ☐	Exposure ☐

Comments:

Notification - Updating Container Disposal Statement per PRN 2007-4

ATTACHMENTS: __X__ **LABELING** __ **CSFs** ____ **DATA** ____ **OTHER**

B	For Arctic Slope Contract Only

Contractor: Arctic Slope	**Contract No.:**	**TOPO/Alt. TOPO:**

Draft Task: Signature _____ ____ (Est. hrs)	**Final Task: Signature** _____ _____ (Total hrs)

C	Reviewers Comments:

Response Code:	Response Date:
1155	14-Jan-2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

JAN 14 2010

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Luanne Jeram, Senior Regulatory Affair Specialist
Lanxess Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Subject: Notification per PR Notice 2007-4
Preventol A14-D
EPA Registration Number: 39967-71
Application Date: December 15, 2009
Receipt Date: December 16, 2009

Dear Ms. Jeram:

This acknowledges receipt of your notification, submitted under the provisions of FIFRA section 3 (c) 9and PR Notice 2007-4.

Proposed Notification:

Updating Container Disposal statement per PRN 2007-4.

General Comments:

The notification is acceptable. A copy has been inserted in your file for future reference.

Should you have further questions concerning this letter, please contact me at (703-308-6416 or by email at mcfarlane.jacqueline@epa.gov or Killian Swift by telephone at 703-308-6346 or by email at swift.killian@epa.gov. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Jacqueline McFarlane
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

EPA	United States Environmental Protection Agency Washington, DC 20460	[ ] Registration [ ] Amendment [X] Other	OPP Identifier Number

Application for Pesticide - Section I

1. Company / Product Number	2. EPA Product Manager	3. Proposed Classification
39967-71	Carlisle	[x] None [ ] Restricted
4. Company / Product (Name)	PM#	
PREVENTOL A14-D	34	

5. Name and Address of Applicant (*include ZIP Code*)

LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

[ ] *Check of this is a new address*

6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [ ] Amendment - Explain Below
- [ ] Resubmission in response to Agency letter dated _____
- [X] Notification - Explain below.
- [ ] Final printed labels in response to Agency letter dated _____
- [ ] "Me Too" Application
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of label change per PR Notice 2007-4. This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling or the Confidential Statement of Formula for this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No		[ ] Yes [ ] No		[ ] Metal [ ] Plastic
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package Wgt	No. per container	[ ] Glass [ ] Paper [ ] Other (Specify)

3. Location of Net Contents Information	4. Size(s) retail Container	5. Location of Label Directions
[ ] Label [ ] Container		

6. Manner in Which Label is affixed to Product [ ] Lithograph [ ] Paper glues [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application.)

Name	Title	Telephone No. (Include Area Code)
Luanne Jeram	Senior Regulatory Affairs Specialist	412-809-4773

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	
Luanne Jeram	Senior Regulatory Affairs Specialist	
4. Typed Name	5. Date	
Luanne Jeram	12/15/09	

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete

34

LANXESS
Energizing Chemistry

Luanne Jeram
Material Protection Products
Regulatory Affairs
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-4773
Fax 412-809-1068
luanne.jeram@lanxess.com
www.US.LANXESS.com

December 15, 2009

VIA COURIER

Ms. ShaRon Carlisle
Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Product: PREVENTOL A14-D
Registration #: 39967-71
Notification of Label Change per PR Notice 2007-4

Dear Ms. Carlisle:

Enclosed is a label change notification for the above listed product per PR Notice 2007-4.

Specifically enclosed are:

1. Application form (EPA Form 8570-1)
2. Proposed label highlighting the updated statements in yellow – 1 copy
3. Proposed label – 1 copy

Please feel free to contact me at 412-809-4773 with any questions.

Sincerely,

Luanne Jeram
Senior Regulatory Affairs Specialist

PREVENTOL® A14-D

TO INHIBIT THE GROWTH OF FUNGI AND ALGAE IN PAINTS, COATINGS, PLASTERS, STUCCO, SEALANTS, CAULKS AND FILLERS

ACTIVE INGREDIENTS:	3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22%
	Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim)	10%
	2-n-octyl-isothiazoline-3-one (NOIT; Octhilinone)	3%
INERT INGREDIENTS		65%
TOTAL		100%

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed or inhaled. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or mist. Wear goggles or face shield, protective clothing and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Product should be stored in an area that is not subject to extreme temperatures. Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If the container is leaking material for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed below.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING: Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available or reconditioning if appropriate. METAL CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

PLASTIC CONTAINERS: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300

EPA Reg. No.: 39967-71

EPA Est. No.:

FIRST AID

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

Have the product Material Safety Data Sheet (MSDS) with you when calling a Poison Control center or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063

INTERNATIONAL 703-527-3887

Net Contents:

Lot No.:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PREVENTOL® A14-D is an antimicrobial preservative to inhibit the grow of fungi and algae in paints, coatings, plasters, sealants, and fillers used for architectural products, finishes and special purpose coatings.

PREVENTOL® A14-D is typically effective when applied at the concentrations shown. All concentrations are based on total formulation weight.

Substrate	Effective Conc. (%)
Paints	0.15 – 2.0%
Coatings	0.15 – 2.0%
Plasters	0.1 – 1.0 %
Stucco	0.1 – 1.0 %
Sealants	0.1 – 1.5 %
Caulks	0.1 – 1.5 %
Fillers	0.1 – 1.5 %

Method of Addition

Typically, PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product (paint, plaster, caulk etc.) to assure universal distribution of the PREVENTOL® A 14-D.

Paints and Coatings: Add 1.5 to 20 lbs. (0.68 to 9.1 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of paint or coating material.

Plasters and Stucco: Add 1 to 10 lbs. (0.45 to 4.5 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of plaster or stucco.

Sealants, Caulks and Fillers: Add 1 to 15 lbs. (0.45 to 6.8 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of sealant, caulk or filler.

Mix well before using this product.

® Preventol is a registered trademark of LANXESS Corporation

LANXESS

LANXESS Corporation
111 RIDC Park West Drive • Pittsburgh, PA 15275-1112

LABEL TEXT DATE: DRAFT NOTIFICATION
Date Revi
Reviewed B

Material to be added to an e-Jacket/Jacket

Reg. No. 39967-71

1. ☑ **Placement within the e-Jacket/jacket:**
   - ☐ **Default: (chronological, top/newest)**
   - ☐ **Description: (PDF page number, i.e., "before page 45")**

   _____

   _____

2. ☐ **Send to Data Extraction contractors this material:**
   - ☐ **Newly stamped accepted label**
   - ☑ **Notification** (acceptable)
   - ☐ **New CSF**
   - ☐ **Other:** _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Lisa McKelvin

Phone: 308-7496 **Division:** AD

Date: 8/12/09

Created July 21/2008

mcf

RISK ASSIGNMENT FORM

Antim. bial Division/Regulatory Manage nt Branch II

A	Completed by Product Manager

PRODUCT REVIEWER: Lisa McKelvin	**RMB** II **TEAM** 34
Description of Action: Notification	**EPA File Symbol/Reg No.** 39967-71

Decision No. 406528	**Submission No.** 845527	**Fee for Service Action Code:**
FQPA Action Code: 332	**Non-FQPA Action Code:**	**PRIA FEE AMOUNT:**

	DAY	MONTH	YEAR
APPLICATION DATE	16	February	2009
EPA PIN DATE	19	February	2009
DATE PM RECEIVED FROM FRONT END	23	February	2009
Date sent to Reviewer			**2009**
DATE SENT TO SCIENCE [VIVIAN COMPLETES]			**2009**
DATE RECEIVED FROM SCIENCE			
NEGOTIATED DUE DATE			DATE DUE OUT OF AGENCY [redacted] March 21, 2009

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

COMMENTS:

Lisa check with Juan to see if the sources are okay.

ATTACHMENTS: ☐-LABELING ☑-CSF(S) ☐-DATA ☐-OTHERS

DATE FEE PAID: **RESPONSE CODE:** 1155 **RESPONSE DATE:** 3/17/09

UNI. . STATES ENVIRONMENTAL PR. TECTION AGENCY
WASHINGTON, DC 20460

MAR 17 2009

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Heather F. Collins
Sr. Regulatory Affairs Specialist
Lanxess Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Subject: Notification in Accordance with PR Notice 98-10
Preventol A14-D
EPA Registration Number: 39967-71
Application: February 16, 2009
Receipt Date: Februrary 19, 2009

Dear Ms. Collins:

This will acknowledge receipt of your notification, submitted under the provisions of PR Notice 98-10, FIFRA section 3 (c) 9.

Proposed Notification:

- Addition of new producers to the CSFs (basic and alternate)
- Add alternate formulation

General Comment:

Based on a review of the material submitted, the following comment applies.

The notification is acceptable.

Should you have any questions concerning this letter, please contact me by telephone at (703) 308-8583 or email address at: mitchell.emily@epa.gov, or Lisa McKelvin by telephone at (703) 308-7496 or email address at: mckelvin.Lisa@epa.gov . When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Emily Mitchell

Emily Mitchell
(Acting) Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

34

LANXESS
Energizing Chemistry

February 16, 2009

VIA COURIER

Heather F. Collins
Material Protection Products
Regulatory Affairs
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3595
Fax 412-809-1068
heather.collins@lanxess.com
www.US.LANXESS.com

Attention: Adam Heyward (34)
Document Processing Desk **(NOTIF)**
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Product: PREVENTOL A14-D
Registration #: 39967-71
Notification: Add an Alternate Formulation and Update Producer

Dear Mr. Heyward:

Enclosed is a notification for the above referenced product. This notification proposes to add Alternate Formulation (3). In addition, I am proposing to add a new Producer to all of the CSFs (Basic, Alternate Formulation (1), Alternate Formulation (2), and Alternate Formulation (3) for this product.

This is being submitted as a Product Chemistry Notification, Source of Active Ingredients, per PR Notice 98-10.

Specifically enclosed are:

1. EPA Form 8570-1
2. CSF for the proposed Basic Formulation (dated 2/16/09) – 1 copy
3. CSF for the current Basic Formulation (dated 8/15/2008) – 1 copy
4. CSF for the proposed Alternate Formulation (1) (dated 2/16/09) – 1 copy
5. CSF for the current Alternate Formulation (1) (dated 8/15/2008) – 1 copy
6. CSF for the proposed Alternate Formulation (2) (dated 2/16/09) – 1 copy
7. CSF for the current Alternate Formulation (2) (dated 8/15/2008) – 1 copy
8. CSF for the proposed Alternate Formulation (3) (dated 2/16/09) – 1 copy
9. Formulator's Exemption (EPA Form 8570-27) – 1 copy
10. Material Safety Data Sheet (MSDS) for [redacted]

Please feel free to contact me at 412-809-3595 with any questions.

Sincerely,

Heather F. Collins

Heather F. Collins
Senior Regulatory Affairs Specialist

Product ingredient source information may be entitled to confidential treatment

United States
EPA **Environmental Protection Agency**
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company / Product Number: 39967-71
2. EPA Product Manager: ADAM HEYWARD
3. Proposed Classification: [x] None [ ] Restricted
4. Company / Product (Name): PREVENTOL A14-D
PM#: 34
5. Name and Address of Applicant (*include ZIP Code*)
LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112
[ ] *Check of this is a new address*
6. **Expedited Review**. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to:
EPA Reg. No.
Product Name

Section - II

[ ] Amendment - Explain Below
[ ] Resubmission in response to Agency letter dated
[X] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated
[ ] "Me Too" Application
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is being submitted as a Product Chemistry Notification, Source of Active Ingredients, per PR Notice 98-10.

This notification proposes to add an additional Alternate formulation (3) and to add a new producer to all the CSFs.

"This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA."

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging		Water Soluble Packaging		2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No		[ ] Yes [ ] No		[ ] Metal [ ] Plastic
* *Certification must be submitted*	If "Yes" Unit Packaging wgt	No. per container	If "Yes" Package Wgt	No. per container	[ ] Glass [ ] Paper [ ] Other (Specify)

3. Location of Net Contents Information: [ ] Label [ ] Container
4. Size(s) retail Container
5. Location of Label Directions
6. Manner in Which Label is affixed to Product: [ ] Lithograph [ ] Paper glues [ ] Stenciled [ ] Other

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary. To process this application.)

Name	Title	Telephone No. (Include Area Code)
Heather F. Collins	Senior Regulatory Affairs Specialist	412-809-3595 / 412-809-1068(fax)

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature: Heather F Collins
3. Title: Senior Regulatory Affairs Specialist
4. Typed Name: Heather F. Collins
5. Date: 2/16/09

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete

Form Approved OMB No. 2070-0060

United States Environmental Protection Agency
Washington, D.C. 20460

EPA

Formulator's Exemption Statement

(40 CFR 152-85)

Applicant's Name and Address	EPA File Symbol/Registration Number
LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112	**39967-71**
	Product Name **Preventol A14-D**
	Date of Confidential Statement of Formula *(EPA form 8570-4)* **February 16, 2009**

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

Diuron

Carbendazim

2-n-Octyl-4-isothiazolin-3-one (NOIT) (New proposed source submitted 2/16/2009)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA Form 8570-4)* for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula *(CSF) (EPA Form 8570-4)* referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source Product Name	Registration Number
Diuron	[redacted]	
Carbendazim		
2-n-Octyl-4-isothiazolin-3-one (NOIT)		

Signature	Name and Title	Date
Heather F Collins	Heather F Collins/ Sr. Regulatory Affairs Specialist	February 16, 2009

EPA Form 8570-27 (Rev. 7-91) White – EPA copy Yellow – Applicant Copy

Product Source information May be Entitled to Confidential Treatment

Pages 118-126 Inert & product ingredient source information may be entitled to confidential treatment

MATERIAL TO BE ADDED TO JACKET

REG # 39967-71

Description: please add material to file

check all that apply		
☐	new stamped accepted label	Send to CSC
☑	new CSF	
☐	notification	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be place in the appropriate bin.

Reviewer's Name: Stacey Grigsby Date: 10/14/08

Phone: 305.6440 Division: AD

ASSIGNMENT FORM

Antimic al Division/Regulatory Manage : Branch II

PRODUCT REVIEWER: Stacey Grigsby	RMB II TEAM 34
Related/Me-Too Product:	EPA File Symbol/Reg No. 39967-71

Decision No. D: 399081	Submission No. 834855	Fee for Service Action Code:
FQPA Action Code: 362	Non-FQPA Action Code:	PRIA FEE AMOUNT:

	DAY	MONTH	YEAR
APPLICATION DATE			2008
EPA PIN DATE			2008
DATE RISK MANAGER RECEIVED FROM FRONT END			2008
21-DAYS START DATE			
21-DAYS END DATE			2008
PM DUE DATE	01	November	

Type of Data:	PSB Product Chemistry	PSB Acute Toxicology	PSB Efficacy	RASSB Environmental Fate	RASSB Ecological Effects	RASSB Chronic Toxicology	RASSB Exposure /Residue

Comments:

Please transfer to Stacey.....

ATTACHMENTS: €-LABELING	€-CSF(S)	€-DATA	€-OTHERS
B	For Arctic Slope Contract Only		
	Contract No.: 0052	*ARCTIC SLOPE/MANAGER*	
	Final Task: Signature _____	_____ (Total hrs)	
C	Reviewer Comments: 1155		

DATE FEE PAID:	RESPONSE CODE: RESPONSE DATE: 10/7/08

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

October 7, 2008

Heather Collins
Lanxess Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Subject:

Preventol A14-D
EPA Registration No. 39967-71
Application Date: August 15, 2008
Receipt Date: August 19, 2008

Dear Ms. Collins:

The following amendment, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amendment, is acceptable.

Proposed Amendment:

- Revised Basic & Alternate Confidential Statement of Formulas (CSFs) #1 and #2 dated 8/15/08

General Comment:

The basic and alternate CSF dated 8/15/2008 supersedes all previously accepted ones.

Copies of the alternate confidential statement of formulas have been inserted in your file for future reference.

Should you have any questions or comments concerning this letter, please contact me via electronic mail: heyward.adam@epa.gov or by telephone (703) 308-6422 or Stacey Grigsby via electronic mail at grigsby.stacey@epa.gov or by telephone at (703)305-6440 during the hours of 8:00am to 4:00pm EST. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Stacey Grigsby

/s/ Adam Heyward
Product Manager (34)
Regulatory Management Branch II
Antimicrobials Division (7510P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

September 2, 2008

DP BARCODE: # 355736
MRID : None

SUBJECT: Preventol A14-D
(Name of Product)

REG. NO. OR FILE SYMBOL: 39967-71

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): **3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron) (035505)**
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazin) (128872)
2-n-octyl-isothiazoline-3-one (Octhilinone) (099901)

CAS Number: 330-54-1, 10605-21-7, 26530-20-1

TEST LAB: Not Applicable

SUBMITTER: Lanxess Corporation

GUIDELINE: Not Applicable

COMMODITIES: Resubmission in Support of New Product Registration

REVIEWER: Alex Traska **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:** 9/4/08

COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

September 2, 2008

MEMORANDUM

Subject: Review of EPA Reg. No. 39967-71

From: Alexander W. Traska, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

9/2/08

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM #34
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Lanxess Corporation.
Action Code: (362) Formula Change, Technical
Due out date: 17 November 2008

Formulations from Label

Active Ingredient(s).....	% by wt
3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron).....	22
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazin)...	10
2-n-octyl-isothiazoline-3-one (NOIT).....	3
Other Ingredients.....	65
Total	100

I BACKGROUND

This resubmission, in support of the new product registration of the subject industrial fungi and algae growth control product, was made by the registrant, Lanxess Corporation.

The registrant, in this resubmission, is responding to the Agency comments made in the June 18, 2008 Product Chemistry Review for the new industrial end-use product, **Preventol A14-D**. This product is an industrial fungi and algae growth inhibiting product for use in paints, coatings, plasters, sealants, caulks and fillers. In the initial new product application, the registrant provided a Basic CSF and Alternate Formulations #1 and #2 for **Preventol A14-D.** The product is produced by a non-integrated system and the three active ingredients utilized are EPA registered.

The following documents were submitted and examined for the chemistry review of this submission: registrant's cover letter dated August 15, 2008, updated/revised Basic CSF dated August 15, 2008, updated/revised Alternate Formulation #1 and #2 both dated August 15, 2008, draft product label EPA dated 04/01/08 and Waiver Request for OPPTS 830.6314 (Oxidizing or Reducing Action) study dated 8/19/08.

II FINDINGS

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the updated/ revised Basic CSF and Alternate Formulations #1 and #2, all dated 8/15/08, agreed with the percentages declared on the product label.

2. The upper and lower certified limits for the active ingredient and other ingredients, given in the proposed new basic and alternate formulations, are acceptable.

3. The active ingredient sources utilized are EPA registered. All other ingredients utilized in the proposed new formulations are approved for use in pesticide formulations.

4. The revised OPPTS 830.6314 waiver request which in greater detail characterized the non-oxidative and non-reducing nature of Preventol A14-D is accepted.

5. The recommended changes to the Basic and Alternate Formulations have been made and are accepted.

III CONCLUSIONS

This resubmission, in support of the new product registration of **Preventol A14-D**, is accepted.

DATA PACKAGE BEAN SHEET

Date: 25-Aug-2008

Decision #: 399081
DP #: (355736)
NON PRIA
Parent DP #:
Submission #: 834855

FQPA

* * * Registration Information * * *

Registration: 39967-71 - PREVENTOL A 14-D

Company: 39967 - LANXESS CORPORATION

Risk Manager: RM 34 - Adam Heyward - (703) 308-6422 Room# PY1 S-8238

Risk Manager Reviewer: Aster Grahn AGRAHN

Sent Date: 21-Aug-2008 Calculated Due Date: 17-Nov-2008 Edited Due Date:

Type of Registration: Product Registration - Section 3

Action Desc: (362) FORMULA CHANGE;TECHNICAL;

Ingredients:

* * * Data Package Information * * *

Expedite: ○ Yes ● No Date Sent: 25-Aug-2008 Due Back:

DP Ingredient:

DP Title:

CSF Included: ● Yes ○ No Label Included: ○ Yes ● No Parent DP #:

90
60

Assigned To		Date In	Date Out	
Organization:	AD / PSB	8/26/08		Last Possible Science Due Date: 03-Oct-2008
Team Name:	CTT	8/26/08		Science Due Date: 10/11/08
Reviewer Name:	ALEX TRASKA			Sub Data Package Due Date: 10/20/08
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

No Additional Data Packages

* * * Data Package Instructions * * *

Product chemistry: Please review the attached cover letter, and revised basic and alternate # 1& 2 CSFs

LANXESS
Energizing Chemistry

August 15, 2008

VIA COURIER

Heather F. Collins
Material Protection Products
Regulatory Affairs
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3595
Fax 412-809-1068
heather.collins@lanxess.com
www.US.LANXESS.com

Document Processing Desk
Attn: Adam Heyward (34) Antimicrobial Division
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Response to letter dated July 30, 2008
Preventol A14-D
EPA Reg. No: 39967-71

Dear Mr. Heyward:

This is in response to the Notice of Pesticide Registration dated July 30, 2008.

The Confidential Statements of Formula (CSF) have been updated per the recommendations in the Product Chemistry Review. To satisfy OPPTS 830.1750 (Certified Limits) I have updated the solvent in the alternate formulation to the standard certified limit. Please see these updated CSFs in Attachment #1.

We have reviewed the protocol for OPPTS 830.6314 (Oxidation/ Reduction). We have found that testing is not applicable to this aqueous product. Please see the Attachment #2 for a detailed qualitative assessment.

Please call me at 412-809-3595 if you have any questions.

Sincerely,

Heather F Collins

Heather F. Collins
Senior Regulatory Affairs Specialist

ATTACHMENT #1

Attached are the updated Confidential Statements of Formula (CSF) for our Preventol A14-D. These CSFs have been updated per the recommendations in the Product Chemistry Review.

PREVENTOL® A14-D

TO INHIBIT THE GROWTH OF FUNGI AND ALGAE IN PAINTS, COATINGS, PLASTERS, STUCCO, SEALANTS, CAULKS AND FILLERS

ACTIVE INGREDIENTS: 3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22%
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim)	10%
2-n-octyl-isothiazoline-3-one (NOIT; Octhilinone)	3%
INERT INGREDIENTS	65%
TOTAL	100%

NOT REVIEWED
In accordance with PR Notice 88-8
Based on Draft Labeling Dated 7/30/08

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed or inhaled. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or mist. Wear goggles or face shield, protective clothing and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Product should be stored in an area that is not subject to extreme temperatures. Store in a cool, dry place and in such a manner as to prevent cross contamination with other pesticides, fertilizers, food, and feed. Handle and open container in a manner as to prevent spillage. If the container is leaking, invert to prevent leakage. If the container is leaking material for any reason or cause, carefully dam up spilled material to prevent runoff. Refer to Precautionary Statements on label for hazards associated with the handling of this material. Do not walk through spilled material. Absorb spilled material with absorbing type compounds and dispose of as directed below.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse (or equivalent). Then puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL: Consult Federal, State or Local disposal authorities for approved alternative procedures.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300
EPA Reg. No.: 39967-74
EPA Est. No.:

FIRST AID

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

Have the product Material Safety Data Sheet (MSDS) with you when calling a Poison Control center or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063

INTERNATIONAL 703-527-3887
Net Contents:
Lot No.:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PREVENTOL® A14-D is an antimicrobial preservative to inhibit the growth of fungi and algae in paints, coatings, plasters, sealants, and fillers used for architectural products, finishes and special purpose coatings.

PREVENTOL® A14-D is typically effective when applied at the concentrations shown. All concentrations are based on total formulation weight.

Substrate	Effective Conc. (%)
Paints	0.15 – 2.0%
Coatings	0.15 – 2.0%
Plasters	0.1 – 1.0 %
Stucco	0.1 – 1.0 %
Sealants	0.1 – 1.5 %
Caulks	0.1 – 1.5 %
Fillers	0.1 – 1.5 %

Method of Addition

Typically, PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product (paint, plaster, caulk etc.) to assure universal distribution of the PREVENTOL® A 14-D.

Paints and Coatings: Add 1.5 to 20 lbs. (0.68 to 9.1 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of paint or coating material.

Plasters and Stucco: Add 1 to 10 lbs. (0.45 to 4.5 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of plaster or stucco.

Sealants, Caulks and Fillers: Add 1 to 15 lbs. (0.45 to 6.8 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of sealant, caulk or filler.

Mix well before using this product.

® Preventol is a registered trademark of LANXESS Corporation

LANXESS

LANXESS Corporation
111 RIDC Park West Drive • Pittsburgh, PA 15275-1112

LABEL TEXT DATE: 8/6/2008

LANXESS
Energizing Chemistry

Jeanne Spiegel
Regulatory Affairs
Material Protection Products
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Phone 412-809-3636
Fax 412-809-1068
Jeanne.Spiegel@lanxess.com
www.US.LANXESS.com

August 15, 2008

VIA COURIER

Attention: Adam Heyward
Document Processing Desk
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

RE: Preventol A14-D
EPA Registration No. 39967-71
Final Printed Labels

Dear Mr. Heyward,

Enclosed please find three (3) copies of the final printed label of the above mentioned product.

Please let me know if there is anything further that you need.

Sincerely,

Jeanne Spiegel

Jeanne Spiegel
Regulatory Affairs Representative

Please read instructions on reverse before com form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
39967-71	Adam Heyward	[X] None [ ] Restricted
4. Company/Product (Name)	PM#	
Preventol A14-D	34	

5. Name and Address of Applicant *(Include ZIP Code)*

LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh PA 15275-1112

[ ] *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[X] Final printed labels in reponse to Agency letter dated 7/30/2008
[ ] "Me Too" Application.
[ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Enclosed please find three copies of the final printed label dated 8/6/2008 for Preventol A14-D.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [X] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jeanne P. Spiegel	Regulatory Affairs Representative	412-809-3686

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Jeanne P. Spiegel	Regulatory Affairs Representative
4. Typed Name	**5. Date**
Jeanne P. Spiegel	8/15/08

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Antimicrobials Division (7510P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

NOTICE OF PESTICIDE:
x Registration
__ Reregistration

(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
39967-71	July 30, 2008

Term of Issuance:
Unconditional

Name of Pesticide Product:
Preventol® A 14-D

Name and Address of Registrant (include ZIP Code):

LanXess Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-112

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA sec 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

2. Make the labeling changes listed below before you release the product for Shipment:

a). Add the phrase "EPA Registration Number 39967-71".

Signature of Approving Official:	Date:
Adam Heyward Product Manager Team-34 Regulatory Management Branch II Antimicrobials Division (7510P)	July 30, 2008

EPA Form 8570-6

b). under the ingredient statement, revise "NOIT" to read "NOIT; Octhilinone".

c). under the pesticide storage section, instructions must be provide on how to store the product to ensure the composition and usefulness of the product and to ensure the integrity of the container.

d). under the pesticide storage section, add instructions that specify what to do if the product leaks or spills from its container.

e). under the pesticide storage section, move the sentence from its current location and place it under the "Pesticide disposal" heading: "Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility."

Refer to PR Notice 83-3 for detailed information.

3. Refer to the enclosed product chemistry review for required corrections on the confidential statement of formulas.

4. Submit three (3) copies of the final printed label prior to releasing this product for sale.

5. The Agency is moving away from review of paper submitted registration applications to electronic review of applications. Therefore, we need your help to make this an efficient and convenient process for both you and the Antimicrobials Division. Accordingly, we are asking you to submit future labeling amendments for this product via the electronic labeling process. Refer to the following website for guidance on electronic submissions, including label: http://www.epa.gov/oppfead1/eds/esr_guidance.htm#overallsub. If you have questions concerning electronic labeling, a list of contacts is available at the following site: http://www.epa.gov/oppfead1/eds/edsgoals.htm#contacts.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Enclosure: (Stamped Labeling and reviews)

PREVENTOL® A14-D

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUL 30 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No.
39967-71

TO INHIBIT THE GROWTH OF FUNGI AND ALGAE IN PAINTS, COATINGS, PLASTERS, STUCCO, SEALANTS, CAULKS AND FILLERS

ACTIVE INGREDIENTS: 3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22%
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TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

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STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

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FIRST AID

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

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IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

Have the product Material Safety Data Sheet (MSDS) with you when calling a Poison Control center or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PREVENTOL® A14-D is an antimicrobial preservative to inhibit the g of fungi and algae in paints, coatings, plasters, sealants, and fillers us for architectural products, finishes and special purpose coatings.

PREVENTOL® A14-D is typically effective when applied at the concentrations shown. All concentrations are based on total formulation weight.

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Paints	0.15 – 2.0%
Coatings	0.15 – 2.0%
Plasters	0.1 – 1.0 %
Stucco	0.1 – 1.0 %
Sealants	0.1 – 1.5 %
Caulks	0.1 – 1.5 %
Fillers	0.1 – 1.5 %

Method of Addition

Typically, PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product (paint, plaster, caulk etc.) to assure universal distribution of the PREVENTOL® A 14-D.

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Mix well before using this product.

® Preventol is a registered trademark of LANXESS Corporation

IN CASE OF EMERGENCY, CALL: CHEMTREC 800-424-9300
EPA Reg. No.: 39967-XX
EPA Est. No.:

INTERNATIONAL 703-527-3887
Net Contents:
Lot No.:

LANXESS

LANXESS Corporation
111 RIDC Park West Drive • Pittsburgh, PA 15275-1112

LABEL TEXT DATE: DRAFT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES
Antimicrobial Division

June 18, 2008

DP BARCODE: # 351320

MRID : #473893-01, #473893-02, #473893-03, #473893-09

SUBJECT: Preventol A14-D
(Name of Product)

REG. NO. OR FILE SYMBOL: 39967-TR

DOCUMENT TYPE: Product Chemistry Review

Manufacturing-use [ ] OR **End-use Product [X]**

INGREDIENTS (PC Codes): **3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron) (035505)**
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazin) (128872)
2-n-octyl-isothiazoline-3-one (Octhilinone) (099901)

CAS Number: 330-54-1, 10605-21-7, 26530-20-1

TEST LAB: Eurofins Product Safety Laboratories & Bayer Industry Services-Analytics

SUBMITTER: Lanxess Corporation

GUIDELINE: OPPTS Test Guidelines 830 Series Group A and B

COMMODITIES: New Product registration

REVIEWER: Alex Traska **ORGANIZATION: AD**

APPROVER: Karen P. Hicks **APPROVED DATE:** 6/18/08
COMMENT:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
PREVENTION,
PESTICIDES
AND TOXIC
SUBSTANCES

June 18, 2008

MEMORANDUM

Subject: Review of EPA Reg. No. 39967-TR

From: Alexander W. Traska, Chemist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

AWT 6/13/08

Thru: Karen P. Hicks, CT Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

To: Adam Heyward PM #34
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: Lanxess Corporation.
Action Code: (A 540) New Product; non-fast track
Due out date: 20 August 2008

Formulations from Label

Active Ingredient(s)	% by wt
3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazin)	10
2-n-octyl-isothiazoline-3-one (NOIT; Octhilinone)	3
Other Ingredients	65
Total	100

I BACKGROUND

This new product registration, for the subject industrial fungi and algae growth control product for use in paints, coatings, plasters, sealants, caulks and fillers was submitted by the registrant, Lanxess Corporation.

The registrant, in this new product application, has requested approval to register a new industrial end-use product, **Preventol A14-D**. This product is an industrial fungi and algae growth inhibiting preservative for use in paints, coatings, plasters, sealants, caulks and fillers. The applicant provided a Basic CSF and Alternate Formulations #1 and #2 covering this new fungi and algae inhibiting product. The product is produced by a non-integrated system. The three active ingredients utilized in the proposed formulation are EPA registered.

The following documents were submitted and examined for the chemistry review of this submission: registrant's cover letter and transmittal document both dated March 27, 2008, pesticide application covering this new product application dated 3/27/08, proposed new Basic CSF 3/27/08, proposed new Alternate Formulation #1 and #2 both dated 3/27/08, draft product label EPA dated 04/01/08, Formulator's Exemption Statement dated March 27, 2008, Certification with Respect to Citation of Data (selective method of support) dated 3/27/2008 and Data Matrix dated 3/27/2008. Also provided was product chemistry data covering OPPTS Test Guideline Series 830 Group A studies under MRID #473893-01 and MRID #473893-09 dated March 27, 2008 and 11/15/2007 respectively and Group B studies under MRID #473893-02 and MRID #473893-03 dated March 27, 2008 and January 24, 2008 respectively.

A preliminary chemistry review of this new product registration was made by CSC Systems & Solutions LLC (CSS) and all relevant comments from the June 3, 2008 CSS review were incorporated into this Product Chemistry Review.

II FINDINGS

1. The requirements of PR Notice 91-2 were satisfied. The nominal concentration of the active ingredients given in the proposed new Basic CSF and Alternate Formulations #1 and #2, all dated 3/27/08, agreed with the percentages declared on the product label.

2. The upper and lower certified limits for the active ingredient and other ingredients, given in the proposed new basic and alternate formulations, are acceptable.

3. The active ingredient sources utilized are EPA registered. All other ingredients utilized in the proposed new formulations are approved for use in pesticide formulations.

4. The study reports under MRID #473893-01 and #473893-09 (Validation of an Analytical Method for the Determination of the Main Components in Preventol A14-D) contained data responding to OPPTS Test Guidelines Series 830, Group A. The data provided were acceptable.

5. The study reports under MRID #473893-02 and #473893-03 contained data responding to OPPTS Test Guidelines Series 830, Group B. The data provided were acceptable. Waiver requests covering OPPTS 830.6315 (Flammability), OPPTS 830.6316 (Explodability), OPPTS 830.6319 (Miscibility) and OPPTS 830.6321 (Dielectric Breakdown) were justified and are accepted. The remaining Group B data studies were performed under GLP standards.

6. The waiver statement "Preventol A14-D contains no oxidizing or reducing agents." addressing OPPTS 830.6314 (Oxidizing or Reducing,Chemical Incompatibility) appears to be insufficient. The registrant's reliance on a qualitative assessment may be sound however to fully satisfy OPPTS 830.6314 requirements, it is recommended that either actual testing of the product's compatibility with common oxidizing agents and metals be conducted or a more detailed qualitative assessment be provided. The reasons for this recommendation are as follows: MSDS for [redacted]

Product ingredient source information may be entitled to confidential treatment

Inert ingredient information may be entitled to confidential treatment

7. Studies covering OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) are currently in progress and will be made available to the Agency on their completion. Results for a minimum of one-year studies are required. Studies must meet GLP requirements.

8. The following revisions to the CSF's are recommended:
   a. Under Item #9, revise ">200°F" to read "N/A." No study results were provided.

   b. Under Item #10, revise "(NOIT)" to read "(NOIT; Octhilinone)."

9. The following revisions to the product label are recommended:

   a. Under the "Active Ingredients" statement, revise "(NOIT)" to read "(NOIT; Octhilinone)."

   b. Under the "Pesticide Storage" section of the product label, provide instructions on how to store the product to ensure the composition and usefulness of the product and to ensure the integrity of the product container.

   c. Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from its container.

   d. Under the "Pesticide Storage" section of the product label, move the following sentence to the "Pesticide Disposal" section, where it is more relevant: "Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility."

III CONCLUSIONS

This new product application, for the new end-use industrial fungi and algae growth inhibiting preservative under the **Preventol A14-D** registration, is accepted with comment.

Registrant should address recommendations noted above in the Findings.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]

Note: This product is not intended for food use.

c. Physical state of product: Liquid

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [ ] No [X]

Note: The CSF lists a flash point of >200°F; however, no study results were provided.

e. The NCs and CLs are acceptable. Yes [X] No []

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Diuron	22	21.34	22.66
Carbendazim	10	9.5	10.5
NOITOcthilinone	3	2.85	3.15

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [ ] No [ ] Not applicable [X]
- Have all impurities of ≥ 0.1% in the product been identified?
Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	473893-01
830.1600 Description of Materials	A	473893-01
830.1620 Production Process[2]	NA	
830.1650 Formulation Process[3]	A	473893-01
830.1670 Formation of Impurities[4]	A	473893-01
830.1700 Preliminary Analysis[5]	[Not required for a non-integrated formulation system.]	
830.1750 Certified Limits[6]	A – Standard certified limits were proposed	473893-01

Data Requirements	Acceptance of Information	MRID No.
	for the basic formulation and alternative formulation (2). A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	
830.1800 Analytical Method[7]	A – A copy of a validated HPLC method was provided for the three active ingredients in the product.	473893-09
830.1900 Submittal of Samples	[Samples are to be provided on request and on a case-by-case basis for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	A	The color of the product was reported to be white to beige at 23°C, based on visual inspection.	473893-03
830.6303 Physical State	A	The product was reported to be a liquid at 23°C, based on visual inspection.	473893-03
830.6304 Odor	A	The product was reported to have a faint odor at 23°C.	473893-03
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	[Not required for end-use products.]	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	A	The product contains no oxidizing or reducing agents. Waiver requested.	473893-02
		[redacted]	
		The applicant's reliance on a qualitative assessment may be	

Product ingredient source information may be entitled to confidential treatment

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		sound; however, the following statement is insufficient: "The product contains no oxidizing or reducing agents."	
830.6315 Flammability/ Flame Extension	A	The product does not contain combustible liquids. Waiver requested.	473893-02
830.6316 Explodability	A	The product contains no potentially explosive agents. Waiver requested.	473893-02
830.6317 Storage Stability	G	A storage stability study is currently underway, and will be provided to EPA once complete. Waiver requested.	473893-02
830.6319 Miscibility[1]	A	The product is not an emulsifiable liquid and it will not be diluted with petroleum solvents.	473893-02
830.6320 Corrosion Characteristics	G	A corrosion characteristics study is currently underway, and will be provided to EPA once complete. Waiver requested.	473893-02
830.6321 Dielectric Breakdown Voltage	A	The product is not designed for an application that will require use around electrical equipment. Waiver requested.	473893-02
830.7000 pH[2]	A	The mean pH of the product was reported to be 5.66 at 22.9-23.2°C. A 1% (w/w) mixture of the product in deionized water was tested. CIPAC MT-75 was referenced. Testing was conducted in compliance with GLP.	473893-03
830.7050 UV/Visible Absorption	NA	[Not required for end-use products.]	
830.7100 Viscosity	A	The mean kinematic viscocity of the product was reported to be 14833.617 centistokes at 20°C and 25052.650 centistokes at 40°C (as determined using a capillary viscometer). Two readings were recorded for each temperature. The	473893-03

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		product showed evidence of non-Newtonian behavior; therefore, only the first measurement (H to I) was reported. ASTM D445/D446 was referenced. Testing was conducted in compliance with GLP.	
830.7200 Melting Point/Melting Range	NA	[Not required for end-use products.]	
830.7220 Boiling Point/Boiling Range	NA	[Not required for end-use products.]	
830.7300 Density/Relative Density/Bulk Density	A	The mean density of the product was reported to be 1.186 g/mL at 20°C. CIPAC MT-3, ASTM D 891-95, and OECD Guideline No. 109 were referenced. Testing was conducted in compliance with GLP.	473893-03
830.7370 Dissociation Constants in Water	NA	[Not required for end-use products.]	
830.7550/830.7560/830.7570 Partition Coefficient	NA	[Not required for end-use products.]	
830.7840/830.7860 Water Solubility	NA	[Not required for end-use products.]	
830.7950 Vapor Pressure	NA	[Not required for end-use products.]	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

June 3, 2008

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF:** Preventol A14-D

DP Barcode: [D351320] **Reg. No. or File Symbol:** [39967-TR]
Manufacturing-Use Product [ ] **End-Use Product** [X]

TO: Karen Hicks, Team Leader
Product Science Branch
EPA Antimicrobials Division

FROM: CSC

THRU: Wallace Powell
Product Science Branch
EPA Antimicrobials Division

APPLICANT: LANXESS Corporation
Pittsburgh, PA

Product Formulation Active Ingredient(s):	**% by Wt.:**
3-(3,4-Dichlorophenyl)-1,1-dimethyl urea (Diuron)	22%
Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim)	10%
2-n-Octyl-isothiazoline-3-one (Octhilinone)	3%

BACKGROUND:

LANXESS Corporation has submitted an application for registration of a new end-use product, Preventol A14-D. This product is an antimicrobial preservative used in architectural products, finishes, and special purpose coatings. The product inhibits the growth of fungi and algae in paints, coatings, plasters, stucco, sealants, caulks, and fillers. The applicant provided a Confidential Statement of Formula (CSF) for the basic formulation (dated March 27, 2008). The applicant also provided CSFs for two alternative formulations (each dated March 27, 2008). The product is produced by a non-integrated system. The registered product, [redacted], is the source of the active ingredient, 3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron). The registered product, [redacted], is the source of the active ingredient, methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim). The registered product, [redacted], is the source of the active ingredient, 2-n-octyl-isothiazoline-3-one (Octhilinone). [redacted] are alternate sources of the active ingredient, 2-n-octyl-isothiazoline-3-one (Octhilinone).

FINDINGS:

Group A Requirements – Product Chemistry Data (MRID 473893-01); and Validation of an Analytical Method for the Determination of the Main Components in Preventol A14-D (MRID 473893-09)

- Group A product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.1750 (Certified Limits). See the "Recommendations" section of this report for deficiencies. See also Table A of this report.

Group B Requirements – Waiver/Bridging Requests for Product Chemistry and Acute Toxicology Data (MRID 473893-02); and Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Viscosity and Density/Relative Density (MRID 473893-03)

- Group B product chemistry data requirements applicable to end-use products have been met, with the exception of OPPTS 830.6314 (Oxidation/ Reduction; Chemical Incompatibility), OPPTS 830.6317 (Storage Stability), and OPPTS 830.6320 (Corrosion Characteristics). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.

- For the study assigned MRID 473893-03, a Good Laboratory Practices (GLP) statement was provided stating that the study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Confidential Statement of Formula

- Certain information on the CSFs must be revised, as noted in the "Recommendations" section of this report.

Product Label

- Certain information on the product label could be improved, as noted in the "Recommendations" section of this report.

RECOMMENDATIONS:

- To satisfy OPPTS 830.1750 (Certified Limits) requirements, an explanation for the basis of the non-standard certified limits for the solvent in alternative formulation (2) must be provided.

- To satisfy OPPTS 830.6314 (Oxidation/ Reduction; Chemical Incompatibility) requirements, it is recommended that either actual testing of the product's compatibility with common oxidizing agents and metals be conducted or a more detailed qualitative

assessment be provided. The MSDS for [redacted]

The applicant's reliance on a qualitative assessment may be sound; however, the following statement is insufficient: "The product contains no oxidizing or reducing agents."

- To satisfy OPPTS 830.6317 (Storage Stability) and OPPTS 830.6320 (Corrosion Characteristics) requirements, results for a minimum of 1 year from a GLP-compliant storage stability and corrosion characteristics study must be provided. Testing of the product is currently underway. Storage and disposal information on the product label needs to be revised if product composition (or packaging) deteriorates over time.

- The following revisions must be made to each of the CSFs:

  - Under Item #9, revise ">200°F" to read "N/A." No study results were provided.

  - Under Item #10, revise "(NOIT)" to read "(NOIT; Octhilinone)."

- The following revisions to the product label are recommended:

  - Under the "Active Ingredients" statement, revise "(NOIT)" to read "(NOIT; Octhilinone)."

  - Under the "Pesticide Storage" section of the product label, provide instructions on how to store the product to ensure the composition and usefulness of the product and to ensure the integrity of the product container.

  - Under the "Pesticide Storage" section of the product label, add instructions that specify what to do if the product leaks or spills from its container.

  - Under the "Pesticide Storage" section of the product label, move the following sentence to the "Pesticide Disposal" section, where it is more relevant: "Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility."

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [ ] No [ ]

Note: This product is not intended for food use.

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [ ] No [X]

Note: The CSF lists a flash point of >200°F; however, no study results were provided.

e. The NCs and CLs are acceptable. Yes [ ] No [X]

Note: Standard certified limits were proposed for alternative formulation (1), with the following exception: non-standard certified limits were proposed for the solvent. An explanation for the basis of the non-standard certified limits for the solvent must be provided.

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Diuron	22	21.34	22.66
Carbendazim	10	9.5	10.5
Octhilinone	3	2.85	3.15

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

• 10% or more of a petroleum distillate:	Yes [ ]	No [X]
• 1.0% or more of methyl alcohol:	Yes [ ]	No [X]
• sodium nitrite at any level:	Yes [ ]	No [X]
• a toxic List 1 inert at any level:	Yes [ ]	No [X]
• arsenic in any form:	Yes [ ]	No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [ ] No [ ]

Note: Storage stability studies are ongoing and have not been completed.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	473893-01
830.1600 Description of Materials	A	473893-01
830.1620 Production Process[2]	NA	

Data Requirements	Acceptance of Information	MRID No.
830.1650 Formulation Process[3]	A	473893-01
830.1670 Formation of Impurities[4]	A	473893-01
830.1700 Preliminary Analysis[5]	*[Not required for a non-integrated formulation system.]*	
830.1750 Certified Limits[6]	A – Standard certified limits were proposed for the basic formulation and alternative formulation (2). U – Standard certified limits were proposed for alternative formulation (1), with the following exception: non-standard certified limits were proposed for the solvent. An explanation for the basis of the non-standard certified limits for the solvent must be provided. A – A signed certification statement was provided, as requested under OPPTS 830.1750(g).	473893-01
830.1800 Analytical Method[7]	A – A copy of a validated HPLC method was provided for the three active ingredients in the product.	473893-09
830.1900 Submittal of Samples	*[Samples are to be provided on a case-by-case basis for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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[1]See Confidential Appendix A for additional information.
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[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

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Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
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830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	*[Not required for end-use products.]*	
830.6314 Oxidation/ Reduction; Chemical Incompatibility	U	The product contains no oxidizing or reducing agents. [redacted] The applicant's reliance on a qualitative assessment may be sound; however, the following	473893-02

Inert & product ingredient source information may be entitled to confidential treatment

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		statement is insufficient: "The product contains no oxidizing or reducing agents."	
830.6315 Flammability/ Flame Extension	A	The product does not contain combustible liquids.	473893-02
830.6316 Explodability	A	The product contains no potentially explosive agents. Waiver requested.	473893-02
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Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		reported. ASTM D445/D446 was referenced. Testing was conducted in compliance with GLP.	
830.7200 Melting Point/Melting Range	NA	*[Not required for end-use products.]*	
830.7220 Boiling Point/Boiling Range	NA	*[Not required for end-use products.]*	
830.7300 Density/Relative Density/Bulk Density	A	The mean density of the product was reported to be 1.186 g/mL at 20°C. CIPAC MT-3, ASTM D 891-95, and OECD Guideline No. 109 were referenced. Testing was conducted in compliance with GLP.	473893-03
830.7370 Dissociation Constants in Water	NA	*[Not required for end-use products.]*	
830.7550/830.7560/830.7570 Partition Coefficient	NA	*[Not required for end-use products.]*	
830.7840/830.7860 Water Solubility	NA	*[Not required for end-use products.]*	
830.7950 Vapor Pressure	NA	*[Not required for end-use products.]*	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency **Office of Pesticide Programs**

Thursday, June 05, 2008

MEMORANDUM

SUBJECT: Acute Toxicity Review for EPA Reg. No.:39967-TR
Product Name: Preventol A14-D
DP Barcode: D351321

FROM: Earl Goad, Biologist
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Earl Goad 6/5/08

THRU: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510P)

TO: Adam Heyward PM#32/Aster Grahn
Regulatory Management Branch II
Antimicrobials Division (7510P)

Applicant: Lanxness Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

PRODUCT FORMULATION FROM LABEL:

PC Codes	Active Ingredient(s):	% by wt.
	3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22.00
	Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim)	10.00
	2-n-octyl-isothiazoline-3-one (NOIT)	3.00
	Other Ingredient(s):	65.00
	Total:	100.00

I) BACKGROUND: The Lanxness Corporation is submitting a set of five Acute Toxicity (Acute: Oral, Dermal, Inhalation; Primary Dermal Irritation and Dermal Sensitization) studies to support the registration of their new Manufactured Use Product (MUP). Additionally a waiver is being requested to satisfy the Primary Eye Irritation requirement. This product is for use in manufacturing to add antimicrobial qualities to a broad range of materials. A primary review of these studies was conducted by the Product Science Branch (PSB)/Antimicrobials Division (AD) contractor, Computer Sciences Corporation (CSC). The Chemistry and Toxicology Team (CTT) conducted a brief secondary review to assure that the studies meet EPA/OPP criteria

This product is identified for the purposes of these Acute Toxicity studies by the alternate name: EXP P108-14.

II) FINDINGS: PSB findings are:

A. The five Acute Toxicity Studies submitted (Oral, Dermal, Inhalation, Skin Irritation, and Dermal Sensitization) are Acceptable.

B. The Primary Eye Irritation study has been waived on the basis of the observed toxicity category I Primary Dermal Irritation. As a result the Primary Eye Irritation has defaulted to toxicity category I.

III) The acute toxicity profile for 39967-TR (Preventol A14-D) is currently:

Study	MRID Number	Toxicity Category	Status
Acute Oral Toxicity	47389304	III	Acceptable
Acute Dermal Toxicity	47389305	IV	Acceptable
Acute Inhalation Toxicity	47389306	III	Acceptable
Primary Eye Irritation	Waived	I	Acceptable
Primary Skin Irritation	47389307	I	Acceptable
Dermal Sensitization	47389308	Sensitizer	Acceptable

IV) LABELING:

A. The signal word for Preventol A14-D is **DANGER** based on the category I for Primary Eye and Dermal Irritation.

B. Precautionary labeling:

Hazards to Humans and Domestic Animals:

Corrosive: Causes irreversible eye damage and skin burns. Harmful if swallowed or inhaled. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or mist. When handling wear goggles or face shield, coveralls worn over long-sleeved shirt and long pants, socks, chemical-resistant footwear, and rubber gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

C. First Aid Statements:

If in eyes:
- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If on skin:
- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If inhaled:
- Move person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. .
- Call a poison control center or doctor for further treatment advice

If swallowed:
- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

For emergency information on [product, use, etc.], call the **National Pesticides Information Center** at 1-800-858-7378, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week. During other times, call the poison control center 1-800-222-1222.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112, 412-809-3595	EPA Registration Number/File Symbol 39967-XX
Active Ingredient(s) and/or representative test compound(s) Diuron Carbendazim 2-n-Octyl-4-isothiazolin-3-one (NOIT)	Date 3/27/2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor	Product Name Preventol A14-D

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offer of compensation (the Data Matrix form should be used for this purpose).	X I am using the selective method of support (or the cite-all option under the selective method), and have included with the forms a completed list of data requirements (the Data Matrix must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]]

X I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Heather F Collins	3/27/2008	Heather F. Collins / Regulatory Affairs Specialist

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

DATA MATRIX

Date March 27, 2008	EPA Reg. No./File Symbol 39967- XX	Page 1 of 3
Applicant's/Registrant's Name & Address LANXESS Corporation, 111 RIDC Park West Drive, Pittsburgh, PA 15275-1112	Product: Preventol A14-D	

Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PRODUCT CHEMISTY				
830.1550	Product identity and composition		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1600	Description of starting materials		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1620	Description of production process		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1650	Description of formulation process		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1670	Discussion of formation of impurities		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1700	Preliminary Analysis of Product		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1750	Certified Limits		39967 (Submitted on 3/27/2008)	OWN	VOLUME 1
830.1800	Enforcement Analytical methods		39967 (Submitted on 3/27/2008)	OWN	VOLUME 9
830.1900	Submittal of Samples		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6302	Color - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.6302	Color - EP		39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.6303	Physical state - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.6303	Physical state - EP		39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.6304	Odor - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	

Signature Heather F Collins	Name and Title Heather F. Collins, Regulatory Affairs Specialist	Date 3/27/2008

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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WASHINGTON, D.C. 20460

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	PRODUCT CHEMISTY – Continued				
830.6304	Odor – EP		39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.6313	Stability - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.6314	Oxidizing or reducing action		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6315	Flammability		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6316	Explodability		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
830.6317	Storage stability		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
830.6319	Miscibility		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.6320	Corrosion Characteristics		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2 (waiver)
830.6321	Dielectric breakdown voltage		39967 (Submitted on 3/27/2008)	OWN	VOLUME 2
830.7000	pH - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7000	pH - EP		39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.7100	Viscosity		39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.7200	Melting Point – TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7220	Boiling Point - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	

Signature	Name and Title	Date
Heather F Collins	Heather F. Collins, Regulatory Affairs Specialist	3/27/2008

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Ingredients: Diuron, Carbendazim, 2-n-Octyl-isothiazolin-3-one (NOIT)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7300	Density – EP		39967 (Submitted on 3/27/2008)	OWN	VOLUME 3
830.7370	Dissociation constant - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7550	Octanol/water partition coefficient - PAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7840	Solubility – TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
830.7950	Vapor Pressure - TGAI	Not applicable	Not applicable (Formulator's Exemption)	FOR	
	ACUTE TOXICOLOGY				
870.1100	Acute oral LD-50,rat		39967	OWN	VOLUME 4
870.1200	Acute dermal LD-50		39967	OWN	VOLUME 5
870.1300	Acute inhalation LC-50,rat		39967	OWN	VOLUME 6
870.2400	Primary eye irritation rabbit		39967	OWN	VOLUME 2 (waiver)
870.2500	Primary dermal irritation		39967	OWN	VOLUME 7
870.2600	Skin sensitization		39967	OWN	VOLUME 8

Signature	Name and Title	Date
Heather F Collins	Heather F. Collins, Regulatory Affairs Specialist	3/27/2008

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830.1600	Description of starting materials				
830.1620	Description of production process				
830.1650	Description of formulation process				
830.1670	Discussion of formation of impurities				
830.1700	Preliminary Analysis of Product				
830.1750	Certified Limits				
830.1800	Enforcement Analytical methods				
830.1900	Submittal of Samples				
830.6302	Color - TGAI				
830.6302	Color – EP				
830.6303	Physical state - TGAI				
830.6303	Physical state - EP				
830.6304	Odor - TGAI				

Signature	Name and Title	Date
Heather F Collins	Heather F. Collins, Regulatory Affairs Specialist	3/27/2008

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830.7000	pH - EP				
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Signature	Name and Title	Date
Heather F Collins	Heather F. Collins, Regulatory Affairs Specialist	3/27/2008

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Signature	Name and Title	Date
Heather F. Collins	Heather F. Collins, Regulatory Affairs Specialist	3/27/2008

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

April 2, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-391763
EPA File Symbol or Registration Number: 39967-TR
Product Name: PREVENTOL A 14-D
EPA Receipt Date: 01-Apr-2008
EPA Company Number: 39967
Company Name: LANXESS CORPORATION

STANLEY C. OSLOSKY
LANXESS CORPORATION
111 RIDC PARK WEST DRIVE
PITTSBURGH, PA 15275-1112

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A540

NEW PRODUCT;NON-FAST TRACK;FIFRA SEC. 2(MM) USES;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-6432.

Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

[redacted] STATES ENVIRONMENTAL PRO[redacted]TION AGENCY
WASHINGTON, D.C. 20460

April 2, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-391763
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Sincerely,

Teresa Downs

Front End Processing Staff
Information Technology & Resources Management Division

Please read instructions on reverse before [redacted]m.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[x] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

874

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
39967-XX TR	Adam Heyward	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
Preventol A14-D	34	

5. Name and Address of Applicant *(Include ZIP Code)*

LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh PA 15275-1112

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[x] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This is a new End Use Product (EUP) registration. This product is a formulation containing Diuron, Carbendazim, and 2-n-Octyl-4-isothiazolin-3-one (NOIT). A product is registered that has the same ai and uses with similar concentrations (but not identical). Similar Product Name: Mergal S 89 Paste (EPA Reg #: 67673-5 (recently transferred from 5383-101)). This is a PRIA II Fee Category A540, New end use product, FIFRA Section 2(mm) uses only, with a 4 month decision time and $4,200 fee. This payment has been made and the pay.gov acknowledgement letter is attached. Contact Name: Heather Collins / Fax number 412-809-1068 / E-mail: heather.collins@lanxess.com

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [x] No	[ ] Yes [x] No	[ ] Yes [x] No	[ ] Metal [x] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[x] Label [ ] Container	60 kg, 1000 kg	[x] on label

6. Manner in Which Label is Affixed to Product: [x] Lithograph / Paper glued / Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Heather F. Collins	Senior Regulatory Affairs Specialist	412-809-3595

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Heather F Collins	Senior Regulatory Affairs Specialist
4. Typed Name	**5. Date**
Heather F. Collins	3/27/08

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

UNIT. .TATES ENVIRONMENTAL PROTECTI. .GENCY
WASHINGTON, D.C. 20460

April 2, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

LANXESS CORPORATION
111 RIDC PARK WEST DRIVE
PITTSBURGH, PA 15275-1112

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 01-APR-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

[redacted] [redacted]

Form Approved OMB No. 2070-0060

United States Environmental Protection Agency
Washington, D.C. 20460

EPA

Formulator's Exemption Statement

(40 CFR 152-85)

Applicant's Name and Address	EPA File Symbol/Registration Number
LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112	**39967-XX**
	Product Name **Preventol A14-D**
	Date of Confidential Statement of Formula *(EPA form 8570-4)* **March 7, 2008**

As an authorized representative of the applicant for registration of the product identified above, I here certify that:

(1) This product contains the following active ingredient(s):

Diuron

Carbendazim

2-n-Octyl-4-isothiazolin-3-one (NOIT)

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging of another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another producer, and is labeled for at least each use for which my product is proposed to be labeled.

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula *(EPA Form 8570-4)* for the above identified product is attached to this statement. That formula statement indicate, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula *(CSF) (EPA Form 8570-4)* referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Active Ingredient	Source Product Name	Registration Number
Diuron	[redacted]	[redacted]
Carbendazim		
2-n-Octyl-4-isothiazolin-3-one (NOIT)		

Signature	Name and Title	Date
Heather F Collins	Heather F Collins/ Regulatory Affairs Specialist	March 27, 2008

EPA Form 8570-27 (Rev. 7-91) White – EPA copy Yellow – Applicant Copy

Product Source may be Entitled to Confidential Treatment

ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

EPA Receipt Date: APR - 1 2008		EPA Reg. Number: 39967-TR		
	Check List Item	Yes	No	N/A
1	Has the **PRIA Fee been Paid**; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an **Application Form** (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a **Confidential Statement of Formula** (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a **Formulator's Exemption Statement** (EPA Form 8570-27) Included in the Submission Package?	X		
5	Is a **Certification with Respect to Citation of Data** (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a **Data Matrix** (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a **Label** Included in the Submission Package?	X		
8	Are **Data** Included in the Submission Package?	X		
9	**Is the Submission an Amendment?**		X	

[redacted] [redacted]

Online Payment

Step 3: Confirm Payment **1 | 2 | 3**

Thank you.
Your transaction has been successfully completed.

Pay.gov Tracking Information

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 24UKQJCL
Agency Tracking ID: 74042920342
Transaction Date and Time: 03/28/2008 16:19 EDT

Payment Summary

Address Information		Account Information		Payment Information	
Account Holder Name:	Heather F. Collins	Card Type:	Visa	Payment Amount:	$4,200.00
Billing Address:	LANXESS Corporation	Card Number:	**********6854	Transaction Date and Time:	03/28/2008 16:19 EDT
Billing Address 2:	111 RIDC Park West Drive	Expiration Date:	3 / 2010		
City:	Pittsburgh	Decision Number:			
State / Province:	PA	Registration Number:			
Zip / Postal Code:	15275-1112				
Country:	USA				

[redacted]

PREVENTOL® A14-D

TO INHIBIT THE GROWTH OF FUNGI AND ALGAE IN PAINTS, COATINGS, PLASTERS, STUCCO, SEALANTS, CAULKS AND FILLERS

ACTIVE INGREDIENTS:	3-(3,4-dichlorophenyl)-1,1-dimethyl urea (Diuron)	22%
	Methyl (1H-benzimidazol-2-yl) carbamate (Carbendazim)	10%
	2-n-octyl-isothiazoline-3-one (NOIT)	3%
INERT INGREDIENTS		65%
TOTAL		100%

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

DANGER CORROSIVE. Causes irreversible eye damage and skin burns. Harmful if swallowed or inhaled. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. Do not get in eyes, on skin, or on clothing. Avoid breathing vapor or mist. Wear goggles or face shield, protective clothing and gloves when handling. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Do not reuse empty container. Triple rinse (or equivalent). Then puncture and dispose of in a sanitary landfill, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

GENERAL: Consult Federal, State or Local disposal authorities for approved alternative procedures.

ENVIRONMENTAL HAZARDS

This product is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

FIRST AID

IF IN EYES: Hold eyes open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.

Have the product Material Safety Data Sheet (MSDS) with you when calling a Poison Control center or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

The LANXESS Pittsburgh Emergency Response Telephone Number is 800-410-3063

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

PREVENTOL® A14-D is an antimicrobial preservative to inhibit the g[redacted] of fungi and algae in paints, coatings, plasters, sealants, and fillers us[redacted] for architectural products, finishes and special purpose coatings.

PREVENTOL® A14-D is typically effective when applied at the concentrations shown. All concentrations are based on total formulation weight.

Substrate	Effective Conc. (%)
Paints	0.15 – 2.0%
Coatings	0.15 – 2.0%
Plasters	0.1 – 1.0 %
Stucco	0.1 – 1.0 %
Sealants	0.1 – 1.5 %
Caulks	0.1 – 1.5 %
Fillers	0.1 – 1.5 %

Method of Addition

Typically, PREVENTOL® A14-D should be added at the beginning of the formulation process mixing of the final product (paint, plaster, caulk etc.) to assure universal distribution of the PREVENTOL® A 14-D.

Paints and Coatings: Add 1.5 to 20 lbs. (0.68 to 9.1 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of paint or coating material.

Plasters and Stucco: Add 1 to 10 lbs. (0.45 to 4.5 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of plaster or stucco.

Sealants, Caulks and Fillers: Add 1 to 15 lbs. (0.45 to 6.8 kg) of PREVENTOL® A14-D to each 1000 lbs. (453 kg) of sealant, caulk or filler.

Mix well before using this product.

® Preventol is a registered trademark of LANXESS Corporation

IN CASE OF EMERGENCY CALL: CHEMTREC 800-424-9300
EPA Reg. No.: 39967-XX
EPA Est. No.:

INTERNATIONAL 703-527-3887
Net Contents:
Lot No.:

LANXESS

LANXESS Corporation
111 RIDC Park West Drive • Pittsburgh, PA 15275-1112

LABEL TEXT DATE: DRAFT

TRANSMITTAL DOCUMENT

Name and Address of Submitter:	LANXESS Corporation 111 RIDC Park West Drive Pittsburgh, PA 15275-1112
Regulatory action in support of which this package is submitted:	**Application for Registration of New EUP with data Preventol A14-D**
Alternate Test Material Name:	**EXP P108-14**
EPA Reg. No./File Symbol:	39967-XX
Transmittal Date:	March 27, 2008

Volume No.	EPA Form No.	Administrative Materials
		Transmittal Document
		Cover Letter
	EPA Form 8570-1	Application for Pesticide Registration (3 copies)
	EPA Form 8570-4	Confidential Statement of Formula (3 copies)
	EPA Form 8570-27	Formulator's Exemption
	EPA Form 8570-34	Citation of Data
	EPA Form 8570-35	Data Matrix
		Product Label (3 copies)
		Pay.gov Acknowledgement

Volume No.	Citation	MRID Number
1	Collins, 2008, Product Chemistry Data. Unpublished study by LANXESS Corporation. 9 pages. With Confidential Attachment. 48 pages. (3 copies).	47389301
2	Collins, 2008, Waiver/Bridging Requests for Product Chemistry and Acute Toxicology Data. Unpublished study by LANXESS Corporation. 7 pages.	47389302
3	Wo, 2008, Physical and Chemical Characteristics: Color, Physical State, Odor, pH, Viscosity, and Density/Relative Density, Study number 23954. Unpublished study by Eurofins | Product Safety Laboratories. 15 pages. (3 copies).	47389303
4	Durando, 2008, Acute Oral Toxicity Up and Down Procedure in Rats, Study number 23955. Unpublished study by Eurofins | Product Safety Laboratories. 16 pages. (3 copies).	47389304
5	Durando, 2008, Acute Dermal Toxicity Study in Rats – Limit Test, Study number 23956. Unpublished study by Eurofins | Product Safety Laboratories. 16 pages. (3 copies).	47389305

6	Durando, 2008, Acute Inhalation Toxicity Study in Rats, Study number 23957. Unpublished study by Eurofins | Product Safety Laboratories. 33 pages. (3 copies).	47389306
7	Durando, 2008, Primary Skin Irritation Study in Rabbits, Study number 23959. Unpublished study by Eurofins | Product Safety Laboratories. 15 pages. (3 copies).	47389307
8	Durando, 2008, Dermal Sensitization Study in Guinea Pigs (Beuhler Method), Study number 23960. Unpublished study by Eurofins | Product Safety Laboratories. 24 pages. (3 copies).	47389308
9	Erstling, 2007, Validation of an Analytical Method for the Determination of the Main Components in Preventol A14-D, Study Number 2007/0115/01. Unpublished study by Bayer Industry Services. 24 pages. (3 copies).	47389309

Company Official: Heather F. Collins
Company Name: LANXESS Corporation
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Backup Contact: Stan Oslosky
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LANXESS Corporation
Phone: 412-809-3577

473893-00

LANXESS
Energizing Chemistry

March 27, 2008

VIA COURIER

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Document Processing Desk **(REGFEE)**
Attn: Adam Heyward (34) Antimicrobial Division
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Subject: Application for New End Use Product
Preventol A14-D
EPA Reg. No: 39967-XX
LANXESS Corporation
111 RIDC Park West Drive
Pittsburgh, PA 15275-1112

Dear Mr. Heyward:

Please find enclosed an application for registration of the LANXESS Corporation pesticide product Preventol A14-D. This product is a formulation containing the active ingredients Diuron, Carbendazim, and 2-n-Octyl-4-isothiazolin-3-one (NOIT).

We believe this to be a PRIA II Fee Category A540, New end use product, FIFRA Section 2(mm) uses only, with a 4 month decision time and $4,200 fee. This payment has been made and the pay.gov acknowledgement letter is attached.

Alternate Test Material Names:
EXP P108-14 is the same as Preventol A14-D. EXP P108-14 was used as an alternate name in preliminary testing for the product.

Similar Registered Product:
A product is registered that has the same active ingredients and uses with similar concentrations (but not identical).
Similar Product Name: Mergal S 89 Paste
EPA Registration Number: 67673-5 (recently transferred from 5383-101).

Please call me at 412-809-3595 if you have any questions.

Sincerely,

Heather F Collins

Heather F. Collins
Senior Regulatory Affairs Specialist

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)
(UP AND DOWN PROCEDURE)

Product Manager: 34
MRID No.: 473893-04

Reviewer: CSC and Earl Goad (CTT)
Completion Date: February 18, 2008
Study No.: 23955

Testing Laboratory: Eurofins | Product Safety Laboratories, East Brunswick, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14
(Test material is the same as Preventol A14-D)
Batch #: UHR 9919-01 / White to beige liquid

Dosage: Limit Test: 5,000 mg/kg (administered as received)
Main Test: 175, 550, 1,750, and 5,000 mg/kg

Species: 9 Rats; Sprague-Dawley derived, albino
Sex: Females. Females were nulliparous and non-pregnant.
Age: Young adult (9-12 weeks old)
Weight: 163-225 grams at experimental start
Source: Ace Animals, Inc., Boyertown, PA
Housing: Temperature Range: 18-21°C
Humidity Range: 30-50%
Photoperiod: 12-hour light/dark cycle
Acclimation: 6-31 days

Conclusion:

1. **Acute Oral LD_{50} (mg/kg)**: Female Rats: 3,129 mg/kg.
95% Confidence Interval: 1,750 to 5,000 mg/kg

2. **Toxicity Category**: III **Classification**: Acceptable

Procedure (Deviations from 870.1100): The deviations recorded here are minor deficiencies in reporting or slight departures from study guidelines, and may not necessarily affect study outcome.

- No procedure deviations were reported.
- The guidelines state that the temperature in the experimental animal room should be 22±3°C. The lower limit of the animal room temperature range (i.e., 18°C) was slightly below this recommended range.
- The guidelines state that animals should be observed individually at least once during the first 30 minutes after dosing. The laboratory reported that the animals were observed during the first several hours post-dosing. Data reported (in Table 2 of the report) identify observations made at 1 hour.

- The guidelines state that body weight changes should be calculated and recorded. Individual body weights of test animals were recorded; however, changes in body weights were not reported.

Results:

Limit Test

Dosing Sequence	Animal No.	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	3101	5,000	D	D

Main Test

Dosing Sequence	Animal No.	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
2	3102	175	S	S
3	3103	550	S	S
4	3104	1,750	S	S
5	3105	5,000	D	D
6	3106	1,750	S	S
7	3107	5,000	D	D
8	3108	1,750	S	S
9	3109	5,000	D	D

S – Survival; D – Death

Observations:

175 mg/kg (1 animal) and 550 mg/kg (1 animal) Dose Levels: Both animals survived, gained body weight, and appeared active and healthy during the study. There were no signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

1,750 mg/kg Dose Level (3 animals): All animals survived exposure to the test substance and gained body weight during the study. One female exhibited reduced fecal volume on Day 1. There were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

5,000 mg/kg Dose Level (4 animals): All animals died within two days of test substance administration. Prior to death, these animals were hypoactive and/or exhibited hunched posture, piloerection, and reduced fecal volume.

Gross Necropsy Findings:

175 mg/kg (1 animal) and 550 mg/kg (1 animal) Dose Levels: No gross abnormalities were noted for either of the animals when necropsied at the conclusion of the 14-day observation period.

1,750 mg/kg Dose Level (3 animals): No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

5,000 mg/kg Dose Level (4 animals): Gross necropsy of the decedents revealed red intestines.

Statistical Analysis:
The *Acute Oral Toxicity (Guide 425) Statistical Program* (Westat, Version 1.0, May 2001) was used for all data analyses, including: dose progression selections, stopping criteria determinations, and/or LD_{50} and confidence limit calculations.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

Product Manager: 34
MRID No.: 473893-05

Reviewer: CSC and Earl Goad (CTT)
Completion Date: February 18, 2008
Study No.: 23956

Testing Laboratory: Eurofins | Product Safety Laboratories, Dayton, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14
(Test material is the same as Preventol A14-D)
Batch #: UHR 9919-01 / White to beige liquid

Dosage: 5,000 mg/kg (applied as received)

Species: 10 Rats; Sprague-Dawley derived, albino
Sex: 5 Males and 5 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-9 weeks old)
Weight: Males: 248-278 grams; Females: 190-207 grams; at experimental start
Source: Ace Animals, Inc., Boyertown, PA
Housing: Temperature: 20-22°C
Humidity: 46-69%
Photoperiod: 12-hour light/dark cycle
Acclimation: 8 days

Summary:

1. **Acute Dermal LD_{50} (mg/kg)**: Male and Female Rats: >5,000 mg/kg

2. **The estimated acute dermal LD_{50} is** greater than 5,000 mg/kg in male and female rats.

3. **Toxicity Category**: IV **Classification**: Acceptable

Procedure (Deviations from 870.1200): The deviations recorded here are minor deficiencies in reporting or slight departures from study guidelines, and may not necessarily affect study outcome.

- No procedure deviations were reported.
- The guidelines state that, after completion of the study in one sex, at least one group of five animals of the other sex is dosed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female groups simultaneously.
- The guidelines state that changes in body weight should be calculated and recorded. Individual body weights of test animals were recorded; however, changes in body weights were not reported.

Results:

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Total
5,000	0 / 5	0 / 5	0 / 10

Observations:
All animals survived exposure to the test substance and gained body weight during the study. Other than dermal irritation noted at all dose sites following exposure, there were no other clinical findings recorded for any animal over the course of the study.

Gross Necropsy Findings:
No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (OPPTS 870.1100)
(UP AND DOWN PROCEDURE)

Product Manager: 34
MRID No.: 473893-04

Reviewer: Karen Hicks
Completion Date: February 18, 2008
Study No.: 23955

Testing Laboratory: Eurofins | Product Safety Laboratories, East Brunswick, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14
Batch #: UHR 9919-01 / White to beige liquid

Dosage: Limit Test: 5,000 mg/kg (administered as received)
Main Test: 175, 550, 1,750, and 5,000 mg/kg

Species: 9 Rats; Sprague-Dawley derived, albino
Sex: Females. Females were nulliparous and non-pregnant.
Age: Young adult (9-12 weeks old)
Weight: 163-225 grams at experimental start
Source: Ace Animals, Inc., Boyertown, PA
Housing: Temperature Range: 18-21°C
Humidity Range: 30-50%
Photoperiod: 12-hour light/dark cycle
Acclimation: 6-31 days

Conclusion:

1. **Acute Oral LD_{50} (mg/kg)**: Female Rats: 3,129 mg/kg
95% Confidence Interval: 1,750 to 5,000 mg/kg

2. **Toxicity Category**: III **Classification**: ___

Procedure (Deviations from 870.1100):

- No procedure deviations were reported.
- The guidelines state that the temperature in the experimental animal room should be 22±3°C. The lower limit of the animal room temperature range (i.e., 18°C) was slightly below this recommended range.
- The guidelines state that animals should be observed individually at least once during the first 30 minutes after dosing. The laboratory reported that the animals were observed during the first several hours post-dosing. Data reported (in Table 2 of the report) identify observations made at 1 hour.

- The guidelines state that body weight changes should be calculated and recorded. Individual body weights of test animals were recorded; however, changes in body weights were not reported.
- The study was conducted using the product, EXP P108-14. A letter from the applicant to EPA (dated March 27, 2008) states that the product, EXP P108-14, is the same as the product, Preventol A14-D, which is the product for which registration is sought.

Results:

Limit Test

Dosing Sequence	Animal No.	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
1	3101	5,000	D	D

Main Test

Dosing Sequence	Animal No.	Dose Level (mg/kg)	Short-Term Outcome	Long-Term Outcome
2	3102	175	S	S
3	3103	550	S	S
4	3104	1,750	S	S
5	3105	5,000	D	D
6	3106	1,750	S	S
7	3107	5,000	D	D
8	3108	1,750	S	S
9	3109	5,000	D	D

S – Survival; D – Death

Observations:

175 mg/kg (1 animal) and 550 mg/kg (1 animal) Dose Levels: Both animals survived, gained body weight, and appeared active and healthy during the study. There were no signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

1,750 mg/kg Dose Level (3 animals): All animals survived exposure to the test substance and gained body weight during the study. One female exhibited reduced fecal volume on Day 1. There were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

5,000 mg/kg Dose Level (4 animals): All animals died within two days of test substance administration. Prior to death, these animals were hypoactive and/or exhibited hunched posture, piloerection, and reduced fecal volume.

Gross Necropsy Findings:
175 mg/kg (1 animal) and 550 mg/kg (1 animal) Dose Levels: No gross abnormalities were noted for either of the animals when necropsied at the conclusion of the 14-day observation period.

1,750 mg/kg Dose Level (3 animals): No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

5,000 mg/kg Dose Level (4 animals): Gross necropsy of the decedents revealed red intestines.

Statistical Analysis:
The *Acute Oral Toxicity (Guide 425) Statistical Program* (Westat, Version 1.0, May 2001) was used for all data analyses, including: dose progression selections, stopping criteria determinations, and/or LD_{50} and confidence limit calculations.

DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (OPPTS 870.1200)

duct Manager: 34
MRID No.: 473893-05

Reviewer: Karen Hicks
Completion Date: February 18, 2008
Study No.: 23956

Testing Laboratory: Eurofins | Product Safety Laboratories, Dayton, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14
Batch #: UHR 9919-01 / White to beige liquid

Dosage: 5,000 mg/kg (applied as received)

Species: 10 Rats; Sprague-Dawley derived, albino
Sex: 5 Males and 5 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-9 weeks old)
Weight: Males: 248-278 grams; Females: 190-207 grams; at experimental start
Source: Ace Animals, Inc., Boyertown, PA
Housing: Temperature: 20-22°C
Humidity: 46-69%
Photoperiod: 12-hour light/dark cycle
Acclimation: 8 days

Summary:

1. **Acute Dermal LD_{50} (mg/kg)**: Male and Female Rats: >5,000 mg/kg

2. **The estimated acute dermal LD_{50} is** greater than 5,000 mg/kg in male and female rats.

3. **Toxicity Category**: IV **Classification**: ___

Procedure (Deviations from 870.1200):

- No procedure deviations were reported.
- The guidelines state that, after completion of the study in one sex, at least one group of five animals of the other sex is dosed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female groups simultaneously.
- The guidelines state that changes in body weight should be calculated and recorded. Individual body weights of test animals were recorded; however, changes in body weights were not reported.

- The study was conducted using the product, EXP P108-14. A letter from the applicant to EPA (dated March 27, 2008) states that the product, EXP P108-14, is the same as the product, Preventol A14-D, which is the product for which registration is sought.

Results:

Reported Mortality

Dose Level (mg/kg)	Number Dead / Number Tested		
	Males	Females	Total
5,000	0 / 5	0 / 5	0 / 10

Observations:
All animals survived exposure to the test substance and gained body weight during the study. Other than dermal irritation noted at all dose sites following exposure, there were no other clinical findings recorded for any animal over the course of the study.

Gross Necropsy Findings:
No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)
(NOSE-ONLY EXPOSURE)

Product Manager: 34
MRID No.: 473893-06

Reviewer: Karen Hicks
Completion Date: February 18, 2008
Study No.: 23957

Testing Laboratory: Eurofins | Product Safety Laboratories, Dayton, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14 (test substance aerosolized as received)
Batch #: UHR 9919-01 / White to beige liquid

Species: 15 Rats; Sprague-Dawley derived, albino
Sex: 5 Males and 10 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-10 weeks old)
Source: Ace Animals, Inc., Boyertown, PA
Weight: Males: 290-313 grams; Females: 209-229 grams; at experimental start
Housing: Temperature: 20-23°C
Humidity: 44-69%
Photoperiod: 12-hour light/dark cycle
Acclimation: 8 or 14 days

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	0.51	55.62
II	2.04	337.4

Summary:

1. **LC_{50} (mg/L) 4-hr exposure**: Male Rats: >2.04 mg/L
Female Rats: between 0.51 and 2.04 mg/L

2. **The estimated 4-hr acute inhalation LC_{50} for EXP P108-14 is greater than 2.04 mg/L in male rats and between 0.51 mg/L and 2.04 mg/L in female rats.**

3. **Average MMAD:** 3.75 µm at the 0.51 mg/L exposure level
3.25 µm at the 2.04 mg/L exposure level

4. **Toxicity Category**: III **Classification**: ___

Procedure (Deviations from 870.1300):

- No procedure deviations were reported.
- The guidelines state that, after completion of the study in one sex, at least one group of five animals of the other sex is exposed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female groups simultaneously.
- The laboratory does not indicate whether animals were acclimated to exposure conditions and heat stress minimized.
- The guidelines state that three to four measurements should be taken during exposure if chamber concentration values and MMAD values taken during the trial run measurements are not within 10 percent of each other. The laboratory reported five trial runs with chamber concentration values ranging from 0.53 to 2.05 mg/L. In addition, only two MMAD values were reported during the trial run. The laboratory conducted only two sample measurements during the test, instead of the three to four measurements recommended in the guidelines.
- The guidelines state that changes in (body) weight should be calculated and recorded. Individual body weights of test animals were recorded; however, changes in body weights were not reported.
- The study was conducted using the product, EXP P108-14. A letter from the applicant to EPA (dated March 27, 2008) states that the product, EXP P108-14, is the same as the product, Preventol A14-D, which is the product for which registration is sought.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number Dead / Number Tested		
	Males	Females	Combined
0.51	---[1]	1 / 5	1 / 5
2.04	0 / 5	2 / 5	2 / 10

[1]Based on the results of the 2.04 mg/L exposure level, only five females were tested at the 0.51 mg/L exposure level.

Chamber Atmosphere

Exp. Conc. (mg/L)	Sample	MMAD (µm)	GSD (µm)	[1]Cumulative % of Particles Collected at Effective Cutoff Diameter (µm)								
				9.0	5.8	4.7	3.3	2.1	1.1	0.7	0.4	0
0.51	1	3.7	1.83	84.2	71.0	62.9	41.7	17.8	3.7	0.9	0.4	0.0
	2	3.8	2.04	84.2	71.5	63.3	42.2	18.4	4.2	1.3	0.5	0.0
2.04	1	3.2	2.16	95.6	80.5	69.3	53.7	26.8	7.4	2.1	0.3	0.0
	2	3.3	2.16	94.4	79.9	67.7	52.1	25.3	7.5	2.2	0.3	0.0

[1]Percent of particles smaller than corresponding effective cutoff diameter.

Chamber Environment During Exposure

Exposure Level (mg/L)	0.51	2.04
Chamber Volume (L)	6.7	6.7
Average Total Airflow (Lpm)	25.7	25.7
Number of Air Changes Per Hour	230	230
Mean Oxygen Content (%)	not reported	not reported
Mean Temperature (°C)	21-23	21-22
Mean Relative Humidity (%)	40-43	68-75

Clinical Observations:
0.51 mg/L Exposure Level: One female died following exposure to the test atmosphere. Prior to death, this animal was hypoactive and exhibited abnormal respiration and hunched posture. Following exposure, surviving animals exhibited clinical signs similar to the above signs and nasal discharge. The surviving animals recovered from these symptoms by Day 9 and appeared active and healthy for the remainder of the study. Although three surviving animals lost body weight through Day 7, all survivors gained body weight over the 14-day observation period.

2.04 mg/L Exposure Level: Two females died within one day of exposure. Prior to death, these animals were hypoactive and exhibited abnormal respiration, abnormal posture, and reduced fecal volume. Following exposure, surviving animals exhibited clinical signs similar to the above signs and ano-genital staining. However, the surviving animals recovered by Day 13 and appeared active and healthy for the remainder of the study. Although all survivors lost body weight through Day 7, all animals gained body weight from Day 7 through Day 14. Two animals did not surpass their pre-exposure body weight.

Gross Necropsy Findings:
0.51 mg/L Exposure Level: Gross necropsy of the decedent revealed discoloration and edema of the lungs. No gross abnormalities were noted for any of the surviving animals when necropsied at the conclusion of the 14-day observation period.

2.04 mg/L Exposure Level: Gross necropsy of the decedents revealed extremely red and edematous lungs. No gross abnormalities were noted for any of the surviving animals when necropsied at the conclusion of the 14-day observation period.

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

Product Manager: 34
MRID No.: 473893-07

Reviewer: Karen Hicks
Completion Date: February 7, 2008
Study No.: 23959

Testing Laboratory: Eurofins | Product Safety Laboratories, East Brunswick, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14
Batch #: UHR 9919-01 / White to beige liquid

Dosage: 0.5 mL (applied as received)

Species: 3 Rabbits; New Zealand, albino
Sex: 3 Females. Females were nulliparous and non-pregnant.
Age: Young adult
Source: Robinson Services, Inc., Clemmons, NC
Housing: Temperature: 19-20°C
Humidity: 32-35%
Photoperiod: 12-hour light/dark cycle
Acclimation: 6 days

Summary:

1. **Toxicity Category**: I

2. **Classification**: _____

Procedure (Deviations from 870.2500):

- No procedure deviations were reported.
- The study was conducted using the product, EXP P108-14. A letter from the applicant to EPA (dated March 27, 2008) states that the product, EXP P108-14, is the same as the product, Preventol A14-D, which is the product for which registration is sought.

Results:
All animals appeared active and healthy over the 24-hour period. Apart from the dermal irritation (i.e., corrosive) noted below, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

One hour after patch removal, all three treated sites exhibited moderate to severe erythema and slight edema. Within 24 hours, large black areas and corrosion were noted in two dose sites.

Due to the severity of irritation observed following the 24-hour evaluation (i.e., corrosive), the study was terminated and all animals were euthanized for humane reasons.

Incidence of Irritation

Time after Patch Removal	Erythema	Edema
30-60 minutes	3 / 3	3 / 3
24 hours	3 / 3	3 / 3

Individual Skin Irritation Scores

Animal No.	Sex	Erythema / Edema	
		Time After Patch Removal	
		30-60 minutes	24 hours[1]
3501	F	3 / 2	4 / 4 [2,3]
3502	F	4 / 2	4 / 4 [2,3]
3503	F	3 / 2	3 / 2
Total		10 / 6	11 / 10
Mean		3.3 / 2.0	3.7 / 3.3

[1]Due to the severity of irritation observed following the 24-hour evaluation (i.e., corrosive), the study was terminated and all animals were euthanized for humane reasons.
[2]Large black areas in the dose site.
[3]Dose site corrosive.

Summary of Skin Irritation Scores[1]

	Time After Patch Removal	
	30-60 minutes	24 hours
Erythema	3.3	3.7
Edema	2.0	3.3
TOTAL (PDI)[2]	5.3	7.0

[1]Average values for three rabbits.
[2]PDI = Average Erythema + Average Edema

DATA REVIEW FOR SKIN SENSITIZATION TESTING (OPPTS 870.2600)
(BUEHLER METHOD)

Product Manager: 34
MRID No.: 473893-08

Reviewer: Karen Hicks
Completion Date: February 18, 2008
Study No.: 23960

Testing Laboratory: Eurofins | Product Safety Laboratories, Dayton, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA), with the following exception: "The stability, uniformity of mixture and verification of concentration of alpha-Hexylcinnamaldehyde Technical (HCA) in its carriers during Eurofins | Product Safety Laboratories historical positive control study were not determined."

Test Material: EXP P108-14
Batch #: UHR 9919-01 / White to beige liquid

Positive Control Material: alpha-Hexylcinnamaldehyde Technical (HCA)
(Historical positive control test completed on October 10, 2007.)

Species:	38 Guinea pigs; Hartley, albino	
Sex:	Range-Finding:	8 Males
	Test Group:	20 Males
	Naïve Control Group:	10 Males
Age:	Young adult (specific age not reported)	
Weight:	Test and Naïve Control Groups: 330-405 grams at experimental start	
Source:	Elm Hill Breeding Labs, Chelmsford, MA	
Housing:	Temperature:	19-22°C
	Humidity:	40-61%
	Photoperiod:	12-hour light/dark cycle
Acclimation:	4-13 days	

Method: Buehler Method

Summary:

1. **Based on these findings and on the evaluation system used, EXP P108-14 is considered to be a contact sensitizer.**

2. **Classification**: ___

Procedure (Deviations from 870.2600):

- No procedure deviations were reported.

- The guidelines require that, as a minimum, the erythema and edema must be graded. The laboratory only graded erythema.
- The study was conducted using the product, EXP P108-14. A letter from the applicant to EPA (dated March 27, 2008) states that the product, EXP P108-14, is the same as the product, Preventol A14-D, which is the product for which registration is sought.

Procedure:
Preliminary Irritation Testing: A group of animals was used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. The fur was removed by clipping the dorsal area and flanks of each guinea pig. This area was divided into four test sites (two sites on each side of the midline) on each animal. The test substance was applied neat (100%) and also diluted with distilled water to yield w/w concentrations of 75%, 50%, 25%, 12%, 6%, 3%, and 1%. Each concentration was applied (0.4 mL each) to a test site using an occlusive 25 mm Hill Top Chamber. The sites were wrapped with non-allergenic Durapore adhesive tape. After 6 hours of exposure, the chambers were removed and the test sites were gently cleansed of any residual test substance. Approximately 24 hours after application, each site was evaluated for local reactions (erythema) according to a scoring system provided in the laboratory report.

From these results, the HNIC (the highest concentration that produced responses in 4 guinea pigs no more severe than two scores of 0.5 and two scores of zero) was established and used for challenge. The HNIC selected for the challenge phase was a 3% w/w mixture in distilled water.

Preparation and Selection of Animals: On the day before initiation, the fur of a group of animals was removed by clipping the dorsal area and flanks. After clipping and prior to initiation, the animals were weighed and the skin was checked for any abnormalities. Only healthy animals without pre-existing skin irritation were selected for test. Animals were re-clipped prior to each dose.

Induction Phase: Once each week for three weeks, four-tenths of a milliliter of the undiluted test substance was applied to the left side of each test animal using an occlusive 25 mm Hill Top Chamber. The chambers were secured in place and wrapped with non-allergenic Durapore adhesive tape to avoid dislocation of the chambers and to minimize loss of the test substance. After the 6-hour exposure period, the chambers were removed and the test sites were gently cleansed of any residual test substance. Approximately 24 and 48 hours after each induction application, readings were made of local reactions (erythema) according to the scoring system.

Challenge Phase: Twenty-seven days after the first induction dose, four tenths of a milliliter of a 3% w/w mixture of the test substance in distilled water (HNIC) was applied to a naïve site on the right side of each animal as a challenge dose, using the procedures described above. These sites were evaluated for a sensitization response (erythema) approximately 24 and 48 hours after the challenge application according to the scoring system. In addition to the test animals, 10 guinea pigs from the same shipment were maintained under identical environmental conditions and were treated with the HNIC of the test substance at challenge only. These animals constituted the "naïve control" group.

Historical Positive Control: The procedures used in this study were validated using alpha-Hexylcinnamaldehyde Technical (HCA) as a positive control substance. The most recent validation, PSL Study #22930, was performed by Eurofins | Product Safety Laboratories. Testing was completed on October 10, 2007. This test was conducted at the Dayton Facility with Hartley strain albino guinea pigs from Elm Hill Breeding Labs following induction and challenge procedures similar to those described above.

Results:

Induction Phase:

Test Animals (100% of undiluted test substance): Very faint to faint erythema (0.5-1) was noted at all test sites throughout the induction phase. Due to desquamation noted at the dose sites following the first and second inductions, the dose site of all animals was relocated to an adjacent naïve site for the second and third induction applications.

Historical Positive Control Animals (HCA applied undiluted): Very faint to faint erythema (0.5-1) was noted for all positive control sites during the induction phase.

Challenge Phase:

Test Animals (3% w/w mixture of the test substance in distilled water): Fourteen of twenty test animals exhibited signs of a sensitization response (faint erythema [1]) 24 hours after challenge. Similar indications persisted at five sites through 48 hours. Very faint erythema (0.5) was noted for most other sites after challenge.

Naïve Control Animals (3% w/w mixture of the test substance in distilled water): Very faint erythema (0.5) was noted for five of ten naïve control sites 24 hours after challenge. Irritation persisted at two of these sites through 48 hours.

Historical Positive Control Animals (75% w/w mixture HCA in mineral oil): Three of ten positive control animals exhibited signs of a sensitization response (faint erythema [1]) 24 hours after challenge. Similar indications persisted at two sites at 48 hours.

Historical Naïve Control Animals (75% w/w mixture of HCA in mineral oil): There was no dermal irritation noted for any of the naïve control sites 24 and 48 hours after challenge.

Sensitization Response Indices (Erythema)

	Incidence of Positive Response[1]		**Severity[2]**	
	Hours		**Hours**	
	24	**48**	**24**	**48**
Test Animals – Challenge	14 / 20	5 / 20	0.85	0.55
Naïve Control Animals – Challenge	0 / 10	0 / 10	0.25	0.00

[1]Animals with scores greater than 0.5.

[2]Sum of the erythema scores divided by the number of animals evaluated.

Test Animal Group Skin Reaction Scores

Treatment Phase	Induction						Challenge	
	1		2[1]		3[1]			
Concentration[2]	100%		100%		100%		3%	
Hours[3]	24	48	24	48	24	48	24	48
Animal No. / Sex								
Test Group								
3601 / M	0.5	0.5	0.5	0.5	0.5	1[4]	0.5	0
3602 / M	1	1	0.5[5]	0.5[5]	0.5	0.5	1	1
3603 / M	1	1	1[5]	1[5]	0.5	1[4]	1	0.5
3604 / M	1	1	0.5	0.5	0.5	0.5	1	0.5
3605 / M	0.5	1[5]	1[5]	1[5]	0.5	0.5	1	1
3606 / M	0.5	0.5	0.5	0	0.5	0.5	1	1
3607 / M	1	0.5	0.5	0.5	0	0	1	0.5
3608 / M	1	1	1[5]	1[5]	0	0	1	1
3609 / M	1	1	0.5	0.5	0.5	0.5	1	0.5
3610 / M	1	1	0.5[5]	0.5	0.5	0.5	1	0.5
3611 / M	0.5	0.5	0.5[5]	0.5[5]	0	0	1	0.5
3612 / M	1	1	0.5	0.5	0.5	0.5	0.5	0
3613 / M	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0
3614 / M	1	1	0.5	0.5	0	0.5	0.5	0.5
3615 / M	0.5	0.5	0	0	0.5	0.5	1	0.5
3616 / M	1	1[5]	0.5	0.5[5]	0	0.5	0.5	0.5
3617 / M	0.5	0.5[5]	0.5	0.5[5]	0.5	0.5	1	0.5
3618 / M	1	1[5]	0.5[5]	0.5[5]	1	0.5	0.5	1
3619 / M	1	1[5]	0.5	0.5	1	1	1	0.5
3620 / M	1	1[5]	1[5]	1[5]	1	1	1	0.5
Naïve Control Group								
3621 / M	--	--	--	--	--	--	0	0
3622 / M	--	--	--	--	--	--	0.5	0.5
3623 / M	--	--	--	--	--	--	0.5	0.5
3624 / M	--	--	--	--	--	--	0.5	0
3625 / M	--	--	--	--	--	--	0	0
3626 / M	--	--	--	--	--	--	0.5	0
3627 / M	--	--	--	--	--	--	0.5	0
3628 / M	--	--	--	--	--	--	0	0
3629 / M	--	--	--	--	--	--	0	0
3630 / M	--	--	--	--	--	--	0	0

[1]Due to desquamation noted at the dose sites following the previous induction, the dose site of all animals was relocated to an adjacent, naïve site for this induction.

[2]The test substance was applied as received.

[3]Hours after induction dose.

[4]Desquamation

[5]Purplish blue discoloration at the dose site.

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (OPPTS 870.1300)
(NOSE-ONLY EXPOSURE)

Product Manager: 34
MRID No.: 473893-06

Reviewer: CSC and Earl Goad (CTT)
Completion Date: February 18, 2008
Study No.: 23957

Testing Laboratory: Eurofins | Product Safety Laboratories, Dayton, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14 (test substance aerosolized as received)
(Test material is the same as Preventol A14-D)
Batch #: UHR 9919-01 / White to beige liquid

Species: 15 Rats; Sprague-Dawley derived, albino
Sex: 5 Males and 10 Females. Females were nulliparous and non-pregnant.
Age: Young adult (8-10 weeks old)
Source: Ace Animals, Inc., Boyertown, PA
Weight: Males: 290-313 grams; Females: 209-229 grams; at experimental start
Housing: Temperature: 20-23°C
Humidity: 44-69%
Photoperiod: 12-hour light/dark cycle
Acclimation: 8 or 14 days

Concentration:

Group	Gravimetric Exposure Concentration (mg/L)	Nominal Concentration (mg/L)
I	0.51	55.62
II	2.04	337.4

Summary:

1. **LC_{50} (mg/L) 4-hr exposure**: Male Rats: >2.04 mg/L
Female Rats: between 0.51 and 2.04 mg/L

2. **The estimated 4-hr acute inhalation LC_{50} for EXP P108-14 is greater than 2.04 mg/L in male rats and between 0.51 mg/L and 2.04 mg/L in female rats.**

3. **Average MMAD:** 3.75 µm at the 0.51 mg/L exposure level
3.25 µm at the 2.04 mg/L exposure level

4. **Toxicity Category**: III **Classification**: Acceptable

Procedure (Deviations from 870.1300): The deviations recorded here are minor deficiencies in reporting or slight departures from study guidelines, and may not necessarily affect study outcome.

- No procedure deviations were reported.
- The guidelines state that, after completion of the study in one sex, at least one group of five animals of the other sex is exposed to establish that animals of this sex are not markedly more sensitive to the test substance. The laboratory appears to have treated both the male and female groups simultaneously.
- The laboratory does not indicate whether animals were acclimated to exposure conditions and heat stress minimized.
- The guidelines state that three to four measurements should be taken during exposure if chamber concentration values and MMAD values taken during the trial run measurements are not within 10 percent of each other. The laboratory reported five trial runs with chamber concentration values ranging from 0.53 to 2.05 mg/L. In addition, only two MMAD values were reported during the trial run. The laboratory conducted only two sample measurements during the test, instead of the three to four measurements recommended in the guidelines.
- The guidelines state that changes in (body) weight should be calculated and recorded. Individual body weights of test animals were recorded; however, changes in body weights were not reported.

Results:

Reported Mortality

Exposure Concentration (mg/L)	Number Dead / Number Tested		
	Males	Females	Combined
0.51	---[1]	1 / 5	1 / 5
2.04	0 / 5	2 / 5	2 / 10

[1]Based on the results of the 2.04 mg/L exposure level, only five females were tested at the 0.51 mg/L exposure level.

Chamber Atmosphere

Exp. Conc. (mg/L)	Sample	MMAD (µm)	GSD (µm)	[1]Cumulative % of Particles Collected at Effective Cutoff Diameter (um)								
				9.0	5.8	4.7	3.3	2.1	1.1	0.7	0.4	0
0.51	1	3.7	1.83	84.2	71.0	62.9	41.7	17.8	3.7	0.9	0.4	0.0
	2	3.8	2.04	84.2	71.5	63.3	42.2	18.4	4.2	1.3	0.5	0.0
2.04	1	3.2	2.16	95.6	80.5	69.3	53.7	26.8	7.4	2.1	0.3	0.0
	2	3.3	2.16	94.4	79.9	67.7	52.1	25.3	7.5	2.2	0.3	0.0

[1]Percent of particles smaller than corresponding effective cutoff diameter.

Chamber Environment During Exposure

Exposure Level (mg/L)	0.51	2.04
Chamber Volume (L)	6.7	6.7
Average Total Airflow (Lpm)	25.7	25.7
Number of Air Changes Per Hour	230	230
Mean Oxygen Content (%)	not reported	not reported
Mean Temperature (°C)	21-23	21-22
Mean Relative Humidity (%)	40-43	68-75

Clinical Observations:
0.51 mg/L Exposure Level: One female died following exposure to the test atmosphere. Prior to death, this animal was hypoactive and exhibited abnormal respiration and hunched posture. Following exposure, surviving animals exhibited clinical signs similar to the above signs and nasal discharge. The surviving animals recovered from these symptoms by Day 9 and appeared active and healthy for the remainder of the study. Although three surviving animals lost body weight through Day 7, all survivors gained body weight over the 14-day observation period.

2.04 mg/L Exposure Level: Two females died within one day of exposure. Prior to death, these animals were hypoactive and exhibited abnormal respiration, abnormal posture, and reduced fecal volume. Following exposure, surviving animals exhibited clinical signs similar to the above signs and ano-genital staining. However, the surviving animals recovered by Day 13 and appeared active and healthy for the remainder of the study. Although all survivors lost body weight through Day 7, all animals gained body weight from Day 7 through Day 14. Two animals did not surpass their pre-exposure body weight.

Gross Necropsy Findings:
0.51 mg/L Exposure Level: Gross necropsy of the decedent revealed discoloration and edema of the lungs. No gross abnormalities were noted for any of the surviving animals when necropsied at the conclusion of the 14-day observation period.

2.04 mg/L Exposure Level: Gross necropsy of the decedents revealed extremely red and edematous lungs. No gross abnormalities were noted for any of the surviving animals when necropsied at the conclusion of the 14-day observation period.

DATA REVIEW FOR SKIN SENSITIZATION TESTING (OPPTS 870.2600)
(BUEHLER METHOD)

Product Manager: 34
MRID No.: 473893-08

Reviewer: CSC and Earl Goad (CTT)
Completion Date: February 18, 2008
Study No.: 23960

Testing Laboratory: Eurofins | Product Safety Laboratories, Dayton, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA), with the following exception: "The stability, uniformity of mixture and verification of concentration of alpha-Hexylcinnamaldehyde Technical (HCA) in its carriers during Eurofins | Product Safety Laboratories historical positive control study were not determined."

Test Material: EXP P108-14
(Test material is the same as Preventol A14-D)
Batch #: UHR 9919-01 / White to beige liquid

Positive Control Material: alpha-Hexylcinnamaldehyde Technical (HCA)
(Historical positive control test completed on October 10, 2007.)

Species: 38 Guinea pigs; Hartley, albino
Sex: Range-Finding: 8 Males
Test Group: 20 Males
Naïve Control Group: 10 Males
Age: Young adult (specific age not reported)
Weight: Test and Naïve Control Groups: 330-405 grams at experimental start
Source: Elm Hill Breeding Labs, Chelmsford, MA
Housing: Temperature: 19-22°C
Humidity: 40-61%
Photoperiod: 12-hour light/dark cycle
Acclimation: 4-13 days

Method: Buehler Method

Summary:

1. **Based on these findings and on the evaluation system used, EXP P108-14 is considered to be a contact sensitizer.**

2. **Classification**: Acceptable

Procedure (Deviations from 870.2600): The deviations recorded here are minor deficiencies in reporting or slight departures from study guidelines, and may not necessarily affect study outcome.

- No procedure deviations were reported.

- The guidelines require that, as a minimum, the erythema and edema must be graded. The laboratory only graded erythema.

Procedure:

Preliminary Irritation Testing: A group of animals was used to determine the highest non-irritating concentration (HNIC) of the test substance prior to the challenge dose. The fur was removed by clipping the dorsal area and flanks of each guinea pig. This area was divided into four test sites (two sites on each side of the midline) on each animal. The test substance was applied neat (100%) and also diluted with distilled water to yield w/w concentrations of 75%, 50%, 25%, 12%, 6%, 3%, and 1%. Each concentration was applied (0.4 mL each) to a test site using an occlusive 25 mm Hill Top Chamber. The sites were wrapped with non-allergenic Durapore adhesive tape. After 6 hours of exposure, the chambers were removed and the test sites were gently cleansed of any residual test substance. Approximately 24 hours after application, each site was evaluated for local reactions (erythema) according to a scoring system provided in the laboratory report.

From these results, the HNIC (the highest concentration that produced responses in 4 guinea pigs no more severe than two scores of 0.5 and two scores of zero) was established and used for challenge. The HNIC selected for the challenge phase was a 3% w/w mixture in distilled water.

Preparation and Selection of Animals: On the day before initiation, the fur of a group of animals was removed by clipping the dorsal area and flanks. After clipping and prior to initiation, the animals were weighed and the skin was checked for any abnormalities. Only healthy animals without pre-existing skin irritation were selected for test. Animals were re-clipped prior to each dose.

Induction Phase: Once each week for three weeks, four-tenths of a milliliter of the undiluted test substance was applied to the left side of each test animal using an occlusive 25 mm Hill Top Chamber. The chambers were secured in place and wrapped with non-allergenic Durapore adhesive tape to avoid dislocation of the chambers and to minimize loss of the test substance. After the 6-hour exposure period, the chambers were removed and the test sites were gently cleansed of any residual test substance. Approximately 24 and 48 hours after each induction application, readings were made of local reactions (erythema) according to the scoring system.

Challenge Phase: Twenty-seven days after the first induction dose, four tenths of a milliliter of a 3% w/w mixture of the test substance in distilled water (HNIC) was applied to a naïve site on the right side of each animal as a challenge dose, using the procedures described above. These sites were evaluated for a sensitization response (erythema) approximately 24 and 48 hours after the challenge application according to the scoring system. In addition to the test animals, 10 guinea pigs from the same shipment were maintained under identical environmental conditions and were treated with the HNIC of the test substance at challenge only. These animals constituted the "naïve control" group.

Historical Positive Control: The procedures used in this study were validated using alpha-Hexylcinnamaldehyde Technical (HCA) as a positive control substance. The most recent validation, PSL Study #22930, was performed by Eurofins | Product Safety Laboratories. Testing was completed on October 10, 2007. This test was conducted at the Dayton Facility with Hartley strain albino guinea pigs from Elm Hill Breeding Labs following induction and challenge procedures similar to those described above.

Results:

Induction Phase:

Test Animals (100% of undiluted test substance): Very faint to faint erythema (0.5-1) was noted at all test sites throughout the induction phase. Due to desquamation noted at the dose sites following the first and second inductions, the dose site of all animals was relocated to an adjacent naïve site for the second and third induction applications.

Historical Positive Control Animals (HCA applied undiluted): Very faint to faint erythema (0.5-1) was noted for all positive control sites during the induction phase.

Challenge Phase:

Test Animals (3% w/w mixture of the test substance in distilled water): Fourteen of twenty test animals exhibited signs of a sensitization response (faint erythema [1]) 24 hours after challenge. Similar indications persisted at five sites through 48 hours. Very faint erythema (0.5) was noted for most other sites after challenge.

Naïve Control Animals (3% w/w mixture of the test substance in distilled water): Very faint erythema (0.5) was noted for five of ten naïve control sites 24 hours after challenge. Irritation persisted at two of these sites through 48 hours.

Historical Positive Control Animals (75% w/w mixture HCA in mineral oil): Three of ten positive control animals exhibited signs of a sensitization response (faint erythema [1]) 24 hours after challenge. Similar indications persisted at two sites at 48 hours.

Historical Naïve Control Animals (75% w/w mixture of HCA in mineral oil): There was no dermal irritation noted for any of the naïve control sites 24 and 48 hours after challenge.

Sensitization Response Indices (Erythema)

	Incidence of Positive Response[1]		Severity[2]	
	Hours		Hours	
	24	48	24	48
Test Animals – Challenge	14 / 20	5 / 20	0.85	0.55
Naïve Control Animals – Challenge	0 / 10	0 / 10	0.25	0.00

[1]Animals with scores greater than 0.5.

[2]Sum of the erythema scores divided by the number of animals evaluated.

Test Animal Group Skin Reaction Scores

Treatment Phase	Induction						Challenge	
	1		2[1]		3[1]			
Concentration[2]	100%		100%		100%		3%	
Hours[3]	24	48	24	48	24	48	24	48
Animal No. / Sex								
Test Group								
3601 / M	0.5	0.5	0.5	0.5	0.5	1[4]	0.5	0
3602 / M	1	1	0.5[5]	0.5[5]	0.5	0.5	1	1
3603 / M	1	1	1[5]	1[5]	0.5	1[4]	1	0.5
3604 / M	1	1	0.5	0.5	0.5	0.5	1	0.5
3605 / M	0.5	1[5]	1[5]	1[5]	0.5	0.5	1	1
3606 / M	0.5	0.5	0.5	0	0.5	0.5	1	1
3607 / M	1	0.5	0.5	0.5	0	0	1	0.5
3608 / M	1	1	1[5]	1[5]	0	0	1	1
3609 / M	1	1	0.5	0.5	0.5	0.5	1	0.5
3610 / M	1	1	0.5[5]	0.5	0.5	0.5	1	0.5
3611 / M	0.5	0.5	0.5[5]	0.5[5]	0	0	1	0.5
3612 / M	1	1	0.5	0.5	0.5	0.5	0.5	0
3613 / M	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0
3614 / M	1	1	0.5	0.5	0	0.5	0.5	0.5
3615 / M	0.5	0.5	0	0	0.5	0.5	1	0.5
3616 / M	1	1[5]	0.5	0.5[5]	0	0.5	0.5	0.5
3617 / M	0.5	0.5[5]	0.5	0.5[5]	0.5	0.5	1	0.5
3618 / M	1	1[5]	0.5[5]	0.5[5]	1	0.5	0.5	1
3619 / M	1	1[5]	0.5	0.5	1	1	1	0.5
3620 / M	1	1[5]	1[5]	1[5]	1	1	1	0.5
Naïve Control Group								
3621 / M	--	--	--	--	--	--	0	0
3622 / M	--	--	--	--	--	--	0.5	0.5
3623 / M	--	--	--	--	--	--	0.5	0.5
3624 / M	--	--	--	--	--	--	0.5	0
3625 / M	--	--	--	--	--	--	0	0
3626 / M	--	--	--	--	--	--	0.5	0
3627 / M	--	--	--	--	--	--	0.5	0
3628 / M	--	--	--	--	--	--	0	0
3629 / M	--	--	--	--	--	--	0	0
3630 / M	--	--	--	--	--	--	0	0

[1]Due to desquamation noted at the dose sites following the previous induction, the dose site of all animals was relocated to an adjacent, naïve site for this induction.

[2]The test substance was applied as received.

[3]Hours after induction dose.

[4]Desquamation

[5]Purplish blue discoloration at the dose site.

DATA REVIEW FOR ACUTE DERMAL IRRITATION TESTING (OPPTS 870.2500)

Product Manager: 34
MRID No.: 473893-07

Reviewer: CSC and Earl Goad (CTT)
Completion Date: February 7, 2008
Study No.: 23959

Testing Laboratory: Eurofins | Product Safety Laboratories, East Brunswick, NJ
Author: Jennifer Durando, B.S.

Quality Assurance (40 CFR §160.12): A Quality Assurance (QA) statement was included. A statement of Good Laboratory Practice (GLP) compliance was included stating that this study meets the requirements of 40 CFR Part 160: U.S. EPA (FIFRA).

Test Material: EXP P108-14
(Test material is the same as Preventol A14-D)
Batch #: UHR 9919-01 / White to beige liquid

Dosage: 0.5 mL (applied as received)

Species: 3 Rabbits; New Zealand, albino
Sex: 3 Females. Females were nulliparous and non-pregnant.
Age: Young adult
Source: Robinson Services, Inc., Clemmons, NC
Housing: Temperature: 19-20°C
Humidity: 32-35%
Photoperiod: 12-hour light/dark cycle
Acclimation: 6 days

Summary:

1. **Toxicity Category**: I

2. **Classification**: Acceptable

Procedure (Deviations from 870.2500):

- No procedure deviations were reported.

Results:
All animals appeared active and healthy over the 24-hour period. Apart from the dermal irritation (i.e., corrosive) noted below, there were no other signs of gross toxicity, adverse pharmacologic effects, or abnormal behavior.

One hour after patch removal, all three treated sites exhibited moderate to severe erythema and slight edema. Within 24 hours, large black areas and corrosion were noted in two dose sites. Due to the severity of irritation observed following the 24-hour evaluation (i.e., corrosive), the study was terminated and all animals were euthanized for humane reasons.

Incidence of Irritation

Time after Patch Removal	Erythema	Edema
30-60 minutes	3 / 3	3 / 3
24 hours	3 / 3	3 / 3

Individual Skin Irritation Scores

Animal No.	Sex	Erythema / Edema	
		Time After Patch Removal	
		30-60 minutes	24 hours[1]
3501	F	3 / 2	4 / 4 [2,3]
3502	F	4 / 2	4 / 4 [2,3]
3503	F	3 / 2	3 / 2
Total		10 / 6	11 / 10
Mean		3.3 / 2.0	3.7 / 3.3

[1]Due to the severity of irritation observed following the 24-hour evaluation (i.e., corrosive), the study was terminated and all animals were euthanized for humane reasons.
[2]Large black areas in the dose site.
[3]Dose site corrosive.

Summary of Skin Irritation Scores[1]

	Time After Patch Removal	
	30-60 minutes	24 hours
Erythema	3.3	3.7
Edema	2.0	3.3
TOTAL (PDI)[2]	5.3	7.0

[1]Average values for three rabbits.
[2]PDI = Average Erythema + Average Edema